Cover Page – Protocol for ClinicalTrials.gov

Grant Title: DiaBetter Together: A Strengths-Based Peer Mentor Program to Support Young Adults with Type 1 Diabetes During the Transition from Pediatrics to Adult Care

NIH Grant Number: R01DK119246

PI: Marisa Hilliard

NCT: NCT04247620

Date: November 14, 2025

November 13, 2025

MARISA HILLIARD
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H-45360 - DIABETTER TOGETHER: A STRENGTHS-BASED, PEER MENTOR TRANSITION RCT FOR YOUNG ADULTS WITH TYPE 1 DIABETES

APPROVAL VALID FROM 11/13/2025 TO 12/2/2030

Dear Dr. HILLIARD

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was reviewed and approved by Expedited procedures on 11/13/2025 by Board 1.

The study **does not require continuing review** but will require a 5 year renewal check in with the IRB Office. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must be submitted to the IRB as an amendment for review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

Research that has been approved by the BCM IRB may be subject to further appropriate review and approval or disapproval by officials of the institution(s) where the research will be conducted. However, those institutional officials may not approve the research if it has not yet been approved by the IRB.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

GABRIEL HABIB, M.D., M.S.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Compare
New Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: **H-45360**
Status: Approved
Initial Submit Date: 4/30/2019
Approval Period: 11/13/2025 - 12/2/2030

Section Aa: Title & PI

A1. Main Title

DIABETTER TOGETHER: A STRENGTHS-BASED, PEER MENTOR TRANSITION RCT FOR YOUNG ADULTS WITH TYPE 1 DIABETES

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

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

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

BCM: Baylor College of Medicine
TCH: Texas Children's Hospital, Clinic

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

Yes

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?

Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?

The BCM PI will register the trial because either:

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

ClinicalTrials.gov Identifier:

NCT04247620

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Developmental demands of late adolescence and early adulthood introduce barriers to successful type 1 diabetes (T1D) self-management and the transition from pediatric to adult systems of care. The need to transfer from pediatric to adult healthcare introduces additional complexities including locating and scheduling with an appropriate provider, obtaining and maintaining insurance coverage, and navigating an unfamiliar system with different expectations for patient-provider interactions and independent self-management. Young adults describe difficulties with the transfer to adult care, including receiving insufficient preparation and support from family, friends, and the healthcare system. Social, informational, and behavioral support tailored to the unique needs of young adults is needed to overcome these barriers and achieve timely transition to adult care and optimal health outcomes.

There are few rigorously developed and researched interventions to support young adults with T1D as they transition from pediatric to adult healthcare, and those with published data show only modest impact on glycemic control and complications. Positive outcomes of existing interventions (e.g., logistical assistance and young adult-centric clinics) include trends toward reducing frequency of missed follow-up visits and hospitalizations for diabetic ketoacidosis, and short-term improvements in glycemic control. However, limitations in the research designs (e.g., nonrandomized designs, small samples, inconsistent reporting of clinical and healthcare utilization outcomes, limited basis in empirically supported theories of health behavior change) raise questions about the magnitude or maintenance of impact. Current healthcare system-based transition interventions have insufficient theoretical foundation, methodological rigor, and evidence. Robust, theory-driven intervention research, compared to standard care and with longer follow-up after the transfer to adult care, is needed.

Section D: Purpose and Objectives

"DiaBetter Together" is a strengths-based peer support intervention delivered to young adults (age 17-25) by trained Peer Mentors (age 20-35) during the transition between pediatric and adult diabetes care. The aims of this proposed randomized controlled trial are to evaluate the impact of the intervention on glycemic control (primary), time to first adult care visit, adherence, and quality of life (secondary) in young adults with T1D.

SUPPLEMENT ACTIVITIES: After participating in the initial "DiaBetter Together" trial, a subset of participants will have the opportunity to complete an optional and additional week (7 days) of follow-up data collection to characterize general and diabetes-specific sleep patterns in a subset of young adults with T1D. We have labeled this optional, additional follow-up data collection as "Supplement Activities" throughout the protocol.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Adult (18-64 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
The only children that may potentially be recruited in this trial are young adults 17 years of age. Study staff will review upcoming scheduled appointments in the diabetes care center, and will screen the electronic medical records of scheduled patients for inclusion and exclusion criteria. Potentially eligible young adults will be sent an informational letter about the study, including instructions to contact study staff to learn more about the study or to opt-out of being contacted about the study. For young adults 17 years of age who do not opt-out, study staff will meet with them and their legal guardian at the next scheduled diabetes clinic visit to confirm eligibility, describe

the study protocol and risks in detail, and answer questions. This conversation will be conducted in a private or quiet/secluded area to protect privacy. Young adults 17 years of age who choose to participate after this process will sign an assent form and their legal guardian will be asked to sign a consent form. Both will receive a copy of the signed forms for their records. Once the young adult participant turns 18, informed consent will be obtained at the next available opportunity. When it is not possible to meet in person with potentially eligible young adults (and their legal guardian if age 17), study staff will contact them by phone or via HIPAA compliant videoconferencing to confirm eligibility, describe the study protocol in detail, and answer questions.

Potential young adult participants and their legal guardians will be assured that participation is voluntary and the decision to participate or not will not impact their health care in any way. They will also be assured that all study participation will be confidential and their responses will not be shared with their care team. The only exception is the A1c value we will collect via dried blood spot for the study, which we will share with their TCH diabetes care provider via EPIC. Study staff will describe the study at a developmentally appropriate level and will ensure participant understanding of the protocol before obtaining written and/or electronic assent and consent. To protect confidentiality, a study ID number will be assigned to the participant and all subsequent data collection will be labeled with this ID number and no other identifiable information. Risks to privacy and confidentiality will be minimized through these study procedures and study staff will be trained in appropriate skills related to recruitment, obtaining informed consent, and data collection and management to avoid undue influence or coercion and to protect confidentiality.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

d) Questionnaire/survey/interview

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

STUDY PARTICIPANTS: parallel two-group design will be used to evaluate the intervention among n=150 young adults randomly assigned to the peer support intervention or usual care (1:1). Participants will be enrolled prior to or at their anticipated final visit in pediatric care at TCH and will be followed for 12 months after leaving pediatrics.

ADVISORY BOARD MEMBERS: There will be no group assignments or controls. Participants will not receive any treatment or intervention. By agreeing to be an advisory board member, participants are agreeing to be contacted about advisory questions that arise in the lab - they are not required to respond to any question, but rather will have the option to agree to answer at any time that they choose.

SUPPLEMENT ACTIVITIES PARTICIPANTS: A subset of up to 35 young adult participants will be asked to enroll to complete the additional follow-up data collection after they have completed the 12-month follow-up for the DiaBetter Together trial. We will enroll participants who completed the control and treatment arms of the initial trial.

Inclusion Criteria:

Young adult participant inclusion criteria: 1) has a diagnosis of type 1 diabetes of at least 1 year; 2) currently receiving care at a TCH Diabetes Care Center location; 3) is between the ages of 17-25 years at enrollment; 4) exhibits fluency in reading/speaking English; & 5) their endocrine provider confirmed plans to transfer to an adult provider within 3-6 months of the upcoming diabetes care appointment.

Peer Mentor participant inclusion criteria: 1) was diagnosed with type 1 diabetes before age 18; 2) has a diagnosis of type 1 diabetes of at least 1 year; 3) is between the ages of 20-35 at enrollment; 4) has been previously treated in pediatric care and is currently treated in adult care; 4) demonstrated interest and ability to effectively deliver the peer intervention & 5) exhibits fluency in reading/speaking English

SUPPLEMENT ACTIVITIES INCLUSION CRITERIA: Young adult participant inclusion criteria: 1) has a diagnosis of type 1 diabetes of at least 1 year; 2) is between the ages of 18-26 years at enrollment in the Supplement Activities; 3) exhibits fluency in reading/speaking English; & 4) has completed participation of either the control or treatment arm of the DiaBetter Together trial.

Exclusion Criteria:

Young adult participant exclusion criteria: 1) serious medical, cognitive, or mental health comorbidity that would preclude ability to provide informed consent or participate in data collection or intervention.

Peer mentor participant exclusion criteria: serious medical, cognitive or mental health comorbidity that would preclude ability to fulfill role or complete questionnaires.

SUPPLEMENT ACTIVITIES EXCLUSION CRITERIA: None. We will select a subset of DiaBetter Together completers based on our enrollment targets for the Supplement Activities, but there are no additional exclusions beyond those for the parent trial.

F2. Procedure

Young Adult Participant Recruitment Recruitment will take place at the TCH Diabetes Care Center in person, via HIPAA compliant videoconferencing, or by phone prior to or following a diabetes appointment. Participants will be patients with T1D age 17-25 who are approaching transfer to adult diabetes healthcare. Study staff will review upcoming scheduled appointments in the diabetes care center, and will screen the electronic medical records of scheduled patients for inclusion and exclusion criteria. Study staff will also confirm with clinic providers that potential participants are approaching transfer to adult care before initiating recruitment activities.

Recruitment letters will be sent to potentially eligible young adults (attached in Section S). Some research studies have documented success with including a brief recruitment video to help those being recruited understand what study participation means. We will include a (link/ QR code) in recruitment letters which will allow young adults to watch a brief, <2 minute video which highlights the most important parts of study participation. These include: who is eligible, why we are doing the study, what participation entails, how long the study lasts, what the intervention is, and data collection with financial incentives. Each person recruited will have the opportunity to view this brief video if they wish. We will post a flyer (Section S) in TCH diabetes clinics to inform patients about our study which will have the QR code for the video.

For young adults who do not opt-out, study staff will meet with them (and their parents if under 18 years of age) at the next scheduled diabetes clinic visit to confirm eligibility, describe the study protocol and risks in detail, and answer questions. This conversation will be conducted in a private or quiet/secluded area to protect privacy. Young adults who meet eligibility requirements and agree to participate will sign all required informed consent and assent forms and will receive a copy of the signed forms for their records. Staff will obtain written informed consent from young adults age 18+, or informed assent with written parent consent for those age <18 (written consent will be obtained after the young adult turns 18). If unable to meet with a young adult in person, we will recruit by phone using the same detailed information presented in person, confirm eligibility, and answer questions. If they agree they will sign the consent form electronically on the study database before they begin questionnaires. Each participant who signs consent electronically will first receive a secure computer generated unique code by email to enter into the BCM Clinical Trials Management System order to access the study consent form. We will also obtain a written signed consent form through the mail system or in person if they come back to TCH.

Baseline Data Collection Following consent, young adult participants will be enrolled in the study and emailed a link and login information to access a password-protected web portal on a secure, HIPAA-compliant server operated through the BCM Clinical Trials Management System, where they will complete baseline questionnaires (see Combined Measures attachment in Section S). To facilitate retention, we will ask participants to provide their contact information, contact information for family/friends who could put us in touch with them if we cannot make follow-up contact, and social media handles for us to contact them via study accounts on social media platforms if we cannot make follow-up contact by any other method.

Upon enrollment, participants will complete a HbA1c dried blood spot at-home test kit if a recent POC or lab drawn value is not available. Each participant will receive a packet by mail which will have all necessary supplies, instructions, and a self addressed prepaid mailer to return to study staff. In order to provide the blood spot, the participant will need to do a finger poke using the lancet provided within the test kit. The blood collection lancet is an FDA 510K cleared device, which is what the patient

will use to poke their finger and collect the blood on the paper. This lancet is designed to provide a deeper finger poke in order for the participant to draw enough blood to fill 3 of the 5 small half inch circles on the blood spot card. This lancet may cause brief discomfort in the finger of the participant. Each participant will be instructed to wash their hands, warm their finger either by rubbing or with warm water, and then clean the finger to be used with an alcohol pad and dry well. They will then poke their finger with the spring loaded lancet and count to 2 before removing. Next, they will wipe away the first drop of blood and then apply gentle pressure and allow a drop of blood to fall on 3 of the small half inch circles. The drop of blood should soak through the card and then the participant will need to air dry the card for 3 hours. Each circle can hold up to 75 to 80 µL of blood. The test itself is cleared by the FDA as a moderately complex test (under lab test regulations). The blood spot cards we will be utilizing (Whatman 903 cards) are approved by the FDA as Class II devices. The HbA1c on filter paper is extracted and measured on the Vitros 4600 HbA1c assay. This assay is correlated with the DCA 2000.

As a supplement to HbA1c, we will also collect continuous glucose data, as recommended by recent consensus guidelines to measure glycemic control with measures beyond HbA1c. We will collect these data directly from participants who are using a continuous glucose monitor (CGM) device. We will collect 14 days of raw data and summary variables (e.g., estimated average glucose, percent time in target glucose range) using cloud-based data platforms either from the manufacturer (e.g., Dexcom Clarity) or using the Texas Children's Hospital healthcare professional access (e.g., Glooko). To use manufacturer platforms, participants will be asked to follow the platform's process to grant data access to study staff via a 12-month code. This is the same process patients use to share CGM data with clinical providers as part of usual care. We will collect data at the same timepoints we are collecting other glycemic control data: baseline and 12 months. We will not collect glucose data for any participant not currently using CGM.

Randomization Participants will be randomized upon completion of baseline questionnaires and return of a completed home A1c kit to intervention or usual care in a 1:1 ratio using a permuted block design. The intervention will begin that day and take place for 12 months.

Peer Mentor Recruitment Peer Mentors will deliver the intervention and will also be enrolled as study participants to permit assessment of their own outcomes. Peer Mentors will be experienced young adults with T1D who have transferred to adult diabetes care. Potential Peer Mentors will be recruited through referrals from previous pediatric providers at TCH, via advertisements in local adult diabetes care centers including BCM (with the support of Dr. McKay, Co-I), local chapters of the College Diabetes Network, local diabetes group newsletters, and social media. Interested Peer Mentors will be screened for eligibility and interest. Peer Mentors will provide informed consent prior to completing questionnaires and being trained.

Peer Mentor Training & Monitoring The PI and study team will train Peer Mentors to deliver the intervention via 2 conveniently scheduled online training sessions each lasting approximately 2 hours, plus additional reading (about 40 minutes) and individual follow-ups with the Peer Mentor liaison as needed. Training will familiarize Peer Mentors with the intervention protocol and materials, introduce and role-play reflective listening skills and basic counseling techniques for interactions with participants, provide instruction and simulation of teaching strengths-based skills, emphasize the importance of helping young adults access their sources of social support, and clarify boundaries of their role as Peer Mentor (e.g., do not provide medical advice/answer medical questions, direct medical questions to diabetes care providers and mental health concerns directed to PI/social worker).

Peer Mentors will have monthly telephone-based individual and group supervision with the study team's Peer Mentor liaison for ongoing training and support and to ensure protocol fidelity. Peer Mentors will also be able to contact the Peer Mentor liaison and PI for any immediate concerns between supervisions. Intervention fidelity will be monitored in an ongoing manner: study staff/PI will review audio-recordings of each Peer Mentor's first session with each participant in comparison to a checklist of intervention components and delivery skills (e.g., asking open-ended questions, personalization). The Peer Mentor liaison will provide feedback based on the checklists, and if <75% of components are addressed adequately, additional training will be provided. The same process will be used to provide feedback and additional training based on Peer Mentors monthly self-assessments of topics addressed in the young adult-Peer Mentor contacts and the young adult-reports of Peer Mentor style and content at the 6-month time point (described below). As-needed booster training sessions for Peer Mentors (in person or via video-conference) will be conducted to maintain fidelity to the intervention protocol and prevent drift.

INTERVENTION Condition After randomization, young adult participants in the intervention group will be assigned to a Peer Mentor. The study team Peer Mentor liaison will pair Peer Mentors with young adults taking into consideration gender, life circumstances (e.g., residential/schooling similarities), race/ethnicity, and availability. Each Peer Mentor will ideally be 1 year older than their assigned participant. Peer Mentors will be assigned 1-3 participants at a time, based on availability and performance. After being assigned, Peer Mentors will schedule a one-hour intervention session with their assigned participant at a convenient time within approximately 2 weeks of being paired together. This session may take place in person, by videoconferencing or telephone (while COVID-19 safety restrictions are in place, in-person meetings will not occur and we will not dictate what platform participants and Peer Mentors use.)

Following an intervention manual, the Peer Mentor will teach behavioral strategies and offer support to the young adult, including (a) teaching and modeling strengths-based skills for goal-setting, problem-solving, and stress management; (b) guiding participants in obtaining support from their social support network (e.g., family, friends); (c) developing a plan for accountability around diabetes management and follow-up in adult care; (d) sharing his/her transition experiences and strategies for

successfully navigating the adult healthcare system; (e) discussing how to prioritize diabetes self-care; and (f) assisting them in accessing diabetes-related resources (e.g., local diabetes groups, apps, social media).

During the first contact, the Peer Mentor will build rapport with the young adult (i.e., learn about his/her diabetes experiences and plans/expectations for the next year), guide them in setting diabetes and transition-related goals, and teach a strengths-based approach to recognizing and celebrating achievements toward those goals. The Peer Mentor will make frequent contact with the young adult via telephone, email, and/or text message (per young adult preference) to introduce the intervention content, help the young adult put it into practice, reinforce successes the young adult has in the transition process, and offer guidance and answer questions about following up in adult care.

(Continued in Section S- "Section F2 092121")

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 186 Worldwide: 186

Please indicate why you chose the sample size proposed:

We plan to enroll 150 young adult participants and up to 36 peer mentor participants (totaling 186 participants).

Sample Size and Power. A difference of 0.5 percentage points (e.g., reduction in HbA1c from 8.5% to 8.0%) is considered a clinically important difference in HbA1c. A sample size of 128 participants (64 per group) would be required to detect a 0.5 percentage point difference in mean HbA1c between treatment arms using an independent two-sample t-test assuming equal variances, common SD=1, and two-sided á=0.05. Therefore, this study will plan to enroll and randomize 150 young adult participants (75/group) to allow for a conservative estimate of 15% attrition based on retention rates ranging between 86-96% in our previous intervention studies.

We will enroll up to 15 advisory board members. We are not collecting data from them so they are not included in sample size and power.

SUPPLEMENT ACTIVITIES SAMPLE SIZE: We plan to invite up to 35 young adult participants to complete the additional follow-up data collection. All participants for the Supplement Activities will be existing participants in the parent trial - there will be no new enrolled participants for the Supplement Activities.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Data Analysis Plan. Baseline demographics and clinical characteristics will be summarized by means with standard deviations, medians with minimum and maximum values, or frequencies with percentages. Summary statistics will be stratified by treatment arm and compared between groups using two-sample t-tests, Wilcoxon rank sum tests, or Fisher¿s exact tests. Approximate normality for continuous measures will be assessed using quantile-quantile plots and Shapiro-Wilks tests. Departures from normality will be address by data transformation (e.g., natural logarithm), categorization, or non-parametric analysis. Statistical significance for the univariable analysis will be assessed at the two-sided 0.05 level; however, significant differences between treatment arms must be due to chance since this is a randomized clinical trial. Missing data on questionnaires are expected to be minimal based on high follow-up data completion rates in preliminary intervention studies and <1% missing item responses in our preliminary study with a similarly-aged sample of young adults. Measures will be scored according to published instructions including rules for handling missing item responses. SAS v9.4 (Cary, NC) will be used for all data summaries and analysis. Aim 1: The primary outcome measure of interest is 12-month HbA1c. An independent, two-sample t-test will be used to compare mean HbA1c between study arms at the 12-month time point. An F test will be used to test the null hypothesis that the variances are equal, and approximate normality will be assessed using QQ-plots and the Shapiro Wilks test. Departures from model assumptions will be addressed by data transformations (e.g., natural logarithm), categorization, or alternative methods of analysis such as Welch¿s t-test approximation or the Wilcoxon rank sum test. Statistical significance will be assessed at the 0.05 level (2-sided). A general linear mixed model will be used to compare mean HbA1c between study arms after adjusting for baseline HbA1c and other clinically relevant covariates. Parameter estimates for the regression model will be assessed at the 0.05 level of significance (2-sided). Secondary outcomes include the time to first adult care visit, treatment adherence, and quality of life. The time to first adult care visit will be compared between treatment arms using the log-rank test statistic for comparing Kaplan-Meier curves. Time will start on the date of the last pediatric care visit. The event of interest is the date of the first adult care visit. Participants who do not follow-up with an adult care provider within 12 months of the last pediatric visit will be censored for the event at the 12-month time point. The log-rank test statistic will be assessed at the two-sided 0.05 level of significance. A Cox Proportional Hazards

regression model will also be used to estimate the Hazards Ratio (95% confidence interval) for adult care follow-up in the intervention versus control groups. Treatment adherence and quality of life will be analyzed using separate general linear mixed models to compare means between study arms over time. The models will include fixed effects for baseline measure, time (6 vs. 12 months), study arm, and the time-arm interaction term. Adherence and quality of life will be analyzed by separate models. Each model will be used to simultaneously compare mean adherence and quality of life measures at the 6- and 12-month time points adjusting for baseline values. Statistical significance will be assessed at the 0.05 level for all secondary hypothesis tests. Aim 2: Regression analysis will be used to test for mediation between study arm and the primary (HbA1c) and secondary outcomes (time to first adult care visit, adherence, quality of life) at 12 months. The 4-step approach recommended by Baron and Kenny105 will be used to assess transition readiness, perceived support, diabetes strengths, diabetes distress, and depressive symptoms at 6 months as mediators for each outcome. Indirect effects will be assessed by computing the difference tween two regression coefficients106,107. Standard errors will be estimated using Bootstrapping. Aim 3: Changes in Peer Mentors¿ self-report outcome measures will be assessed using paired t-tests or the Wilcoxon signed rank test. Statistical significance will be assessed at the 0.05 level of significance (2-sided). General linear mixed models may also be used to test the association between changes in measures over time with demographic and clinical characteristics. The models will include time (baseline vs. follow-up), covariates, and the covariate-time interaction term. The matrix of correlated residuals will assume an unstructured format.

SUPPLEMENT ACTIVITIES DATA ANALYSIS: We will conduct descriptive statistics (means with standard deviations, medians with minimum and maximum values, or frequencies with percentages) and basic correlations between variables of interest. We will use NVivo software to code qualitative transcripts and conduct hybrid thematic analysis.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

While it is unlikely that participants will experience any risk, there may be minimal distress associated with completing questionnaires that ask about feelings related to having diabetes. Participants will be informed that they may skip any questions that they find uncomfortable or that they prefer not to answer. The alternative to participation in this project is to not participate.

All data will be strictly confidential with identifying information being kept separately from questionnaires and blood sample. Participants will have a number assigned to their data. All data will be stored in a locked file cabinet and will only be examined by trained research professionals or in locked offices in CLIA-Certified laboratories at BCM/TCH (for A1c data).

There is a small risk that the lancet used for the blood collection could cause minor, temporary discomfort to the participant's finger. The lancet is designed to provide a deeper finger poke than what the participant uses daily for blood glucose checks. The lancet will allow for the amount of blood required to fill 3 small half inch circles. We will let patients know that their A1c data will be available to their TCH providers. A1c data will be stored in compliance with the institution's laboratory's protocols and procedures. Samples will be discarded seven days after receipt and processing. Storage location is WT.BB1.100 and badge access is required for this space.

Participants will complete the PROMIS Depression Short Form, a screening measure of 4 affective symptoms of depression. We will follow the same safety measures as we have used successfully in other studies. Study staff will review scores on this measure within 2 business days of completion - if a participant's score is elevated (T-scores 60+ [1 SD above the normative sample mean]), they will notify the PI within 2 business days. The PI (licensed psychologist) or a study-affiliated licensed behavioral healthcare provider will call participants with elevated scores within 2 business days of being notified, for further assessment and to provide a list of local mental health resources. For participants under age 18 with elevated scores, we will follow-up with the participant's parent/legal guardian (who provided consent) and will attempt to also follow-up with the participant. The PI/licensed behavioral healthcare provider will make daily attempts to contact the participant for 3 days to follow-up. Following the telephone call (completed or attempted), the team will send a follow-up letter and a list of local mental health providers (attached in Section S)

Additionally, if participants express any distress related to completing other questionnaires, the PI (a licensed clinical psychologist) and study staff will be available to discuss concerns and make referrals to mental health professionals as needed.

As with any study, there are risks associated with loss of confidentiality. To minimize these risks, all efforts will be made to fully comply with federal and HIPAA regulations to avoid disclosure of protected health information (PHI). Study staff will be carefully trained and supervised to adhere to regulations and reduce risks to confidentiality, including completion of required training modules (e.g., responsible conduct of research). Additionally, participating Peer Mentors will be trained to not share confidential information with anyone outside the study.

It is also possible that participants in both conditions will experience diabetes-related medical deterioration. Participation in this study will not impact participants' access to their usual diabetes care provided through Texas Children's Hospital diabetes care centers. Any medical questions that participants ask during the course of the study will be referred to the medical team per TCH policy until the participant has established diabetes medical care with an adult provider. The medical director Co-I on this study (Dr Lyons and Dr McKay) will also be available at monthly meetings or on a as-needed basis to address any medical or health-related risks that arise during the course of the study. For any participants that are unable to access TCH medical care (e.g. lapse in medical insurance), the medical director Co-I will provide guidance as to where to receive care (e.g. Harris Health). Additionally, participating Peer Mentors will be instructed to not give participating young adults medical advice and to direct all medical questions to the young adults' medical team. Compliance with this will be monitored by the study staff member who will oversee Peer Mentors and maintain regular contact with them throughout the study.

SUPPLEMENT ACTIVITIES: In addition to the potential risks/discomforts and related procedures for the initial data collection, an additional risk for the Supplement Activities may include discomfort while wearing an actigraphy wrist device. Participant will also be informed that they may remove the actigraphy device if they experience discomfort. Participants who endorse significant sleep problems (>5 on the PSQI) will be provided with sleep resources including sleep hygiene tips, links to reputable websites, and contact information for the Baylor Sleep Medicine Clinic. As in the parent trial, to minimize risks related to completing potentially distressing questionnaires or interview questions, participants will be informed that they may refuse to answer any questions included in the questionnaires or in the qualitative interview. The supplemental activities will use the same methods implemented by the parent trial to minimize risks related to confidentiality of sensitive personal health and behavioral information. To minimize risks related to the confidentiality of sensitive personal health and behavioral information, all efforts will be made to fully comply with federal and HIPAA regulations to avoid disclosure of protected health information (PHI).

Participants will complete the PROMIS Depression Short Form, a screening measure of 4 symptoms of depression. We will follow the same safety measures we are using in the parent trial. Study staff will review scores on this measure within 2 business days of completion - if a participant's score is elevated (T-scores 60+ [1 SD above the normative sample mean]), they will notify the PI within 2 business days. The PI (licensed psychologist) or a study-affiliated licensed behavioral healthcare provider will call participants with elevated scores within 2 business days of being notified, for further assessment and to provide a list of local mental health resources. The licensed behavioral healthcare provider will make daily attempts to contact the participant for 3 days to follow-up. Following the telephone call (completed or attempted), the team will send the same follow-up letter and list of local mental health providers provided to participants in the parent trial (attached in Section S).

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There are no known direct benefits to subjects to participating in this research. Participant young adults allocated to the intervention condition (DiaBetter Together) may gain skills in managing diabetes and other daily stressors, as well as find support from their interactions with the Peer Mentor as they transition from pediatric diabetes care to adult diabetes care.

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

The overall goal of this randomized controlled trial is to evaluate the impact of a strengths-based peer support intervention on glycemic control, time to first adult care visit, adherence, and quality of life in young adults with T1D.

The goal of the advisory board is to ensure that the perspectives of people with type 1 diabetes are reflected in the research conducted by study staff. Obtaining feedback on our study ideas, materials, and procedures will help ensure our work is relevant to and reflective of the target population. Thus, the scientific outcomes on a broader level should be more relevant to people with diabetes.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Yes, the potential benefits of this research outweigh the possible risks. The potential risks are minimal, and the possible emotional distress is unlikely to have short- or long-term impact on participants' health or well-being. However, the benefits to individuals and society have the potential to have a lasting impact on a vulnerable group of individuals in a growing population of youth with diabetes.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A chart review will be conducted prior to research staff approaching young adults to determine age, diagnosis, whether the young adult is approaching transfer to adult care and other eligibility criteria.

If the study team receives recommendations for potential advisory board members who are patients at TCH, we will conduct a brief chart review to ensure they meet study criteria before contacting them.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

This information will be used to confirm age and diagnosis.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

We follow standard communication procedures in diabetes clinic to ensure participants are not overly burdened by being recruited for more than one study at a time.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

We would not be able to determine if a young adult was eligible to be approached since age, diagnosis, and whether the young adult is approaching transfer to adult cares are a major part of this study.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

N/A

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

Our electronic medical record will be screened by trained study staff.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Reasons for a young adult or potential advisory board member declining may be documented. There will be no study data to destroy unless a young adult declines participation after they are approached. In this case all written information will be destroyed (shredded) at TCH.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Our department, as part of BCM and TCH, follows all required privacy laws. Nothing will be shared except for the purpose of our research.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

Will additional pertinent information be provided to subjects after participation?
Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.
Pertinent information (e..g., a summary of study findings) will be provided via telephone, letter, or email.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

Advisory board participation involves no more than minimal risk to participants. Advisory board activities do not involve any activities for which written consent is normally required - they will receive no interventions/treatments and will provide very limited PHI, which will not be documented or analyzed.

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

YOUNG ADULT PARTICIPANTS CONSENT PROCEDURE: Study staff will review diabetes clinic schedules to identify potentially eligible patients. They will confirm with providers if the patients are approaching their final pediatric diabetes care visit. Study staff will then screen young adults' medical charts to further assess eligibility.

Potentially eligible young adults will be sent an informational letter about the study 1-2 weeks prior to their next diabetes visit, including instructions to contact study staff to learn more about the study or to opt-out of being contacted about the study (See attachment in Section S). Letters will be sent via USPS, and for people with active MyChart accounts via the MyChart communication portal. We will also hang a flyer in the Texas Children's Diabetes Care Clinics with general and contact information (attachment in Section S). For young adults who do not opt-out, study staff will attempt to reach them by phone prior to their diabetes clinic visit to confirm eligibility, describe the study protocol and potential risks, and answer questions. If study staff does not reach them by phone, they will meet with them at the diabetes clinic visit to confirm eligibility, describe the study protocol and potential risks/benefits in detail, and answer questions. Potential participants will be given a written summary of the study and will be given opportunities to ask questions and will have as much time as they wish to consider if they want to participate. Those who pass screening and want to enroll will sign all required informed consent forms. Young adults over 18 years of age will sign an informed consent form for their own participation. If the young adult is under 18 years old, study information will be reviewed in the presence of a legal guardian. The legal guardian will sign an informed consent form for the young adult's participation, and the young adult will sign an assent form for their own participation. Participants will receive a copy of the signed forms for their records. Originals of the signed consent and assent forms will be stored in locked filing cabinets accessible only by trained study staff and agencies/individuals with legal rights or authority to inspect the records. No study procedures will occur until after signed informed consent and assent are obtained. Any participant who turns 18 during the course of the study will be asked to sign informed consent documents as an adult.

If unable to meet with a young adult in person, we will recruit by phone or videoconferencing using the same detailed information presented in person, confirm eligibility, and answer questions. For those potential participants that study staff is unable to reach by phone or via MyChart, if an email is available in their TCH electronic medical record (EPIC), study staff will send an email (See attachment Section S) with the study information from the recruitment letter with our contact information. If they agree they will sign the consent form electronically on the study database before they begin questionnaires. Each participant (parent or guardian) who signs consent electronically will first receive a BCM CTMS generated unique code by email in order to access consent forms. This email will automatically be sent when study staff enters participants' information into the secure study database after the participant agrees verbally to enroll. Each unique 1 time code expires within 15 minutes. If the participant is unable to sign the electronic consent form within the 15 minutes, study staff will trigger another email at a convenient time for the participant with a new unique code for the participant to enter before they sign consent. We will also obtain a written signed consent form by mail or in person.

(continued in Section S, "Section J2 Supplement Activities 11.18.21")

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

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

Identifiable biospecimens
Yes

Will identifiable biospecimens be stored for future research?
NA

If yes, is the storage of biospecimens optional for subjects?
NA

Will identifiable private information be stored for future research?
NA

If yes, is the storage of information optional for subjects?
NA

Questionnaire, Survey, and/or subject diary
NA

Other:
No

At what institution will the physical research data be kept?
Texas Children's Hospital- Feigin Center Storage location for dried blood spot sample is Texas Children's Hospital- WT.BB1.100 and badge access is required for this space. Samples will be saved for up to 7 days.

How will such physical research data be secured?
All research data that is collected electronically will be entered in a password-protected database and stored on a secure server, accessible only by the PI and study staff. All research data that are collected via pencil and paper materials will be entered into the same secure database and all hard copies will be stored in a locked filing cabinet in a locked office, accessible only to the PI and study staff. All study data (hard copies and electronic files) will be coded by being labeled with a study number and not with identifiable personal information. The only document linking participant names and IDs will be the signed consent forms, and will be stored separately from study data and will be appropriately secured and accessible only to the PI.

At what institution will the electronic research data be kept?
BCM secure server sharedrive, BCM's Microsoft OneDrive, BCM Clinical Trials Management System (CTMS)

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
Yes, (describe below):
Audio recordings only identified by study ID may be kept on BCM's Microsoft OneDrive (requires login) temporarily. OneDrive's study folders will only be accessible by study staff. Recordings will be transferred to BCM secure server study share drive folders on a regular basis by study staff. BCM Clinical Trials Management System (CTMS) will be utilized for survey data collection and other study related forms.

Participant addresses will be entered into BCM's Microsoft OneDrive without any identifying information for geocoding.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

Yes, identify the classes of the persons:
Audio-recorded interviews with study participants (e.g., satisfaction interviews upon study completion) may be transcribed by medical transcriptionists (we use Landmark Associates) We will collect Hemoglobin A1c data from all participants at two timepoints in the study. These results will be entered into each participant's electronic medical record (EPIC) at Texas Children's Hospital in order to share this data with the participant's medical provider. Due to the COVID pandemic, many patients in the Diabetes Care Center at Texas Children's Hospital have not completed a recent A1c so we are sharing this data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

We don't anticipate any transmission of research data (sensitive or non-sensitive) with collaborators outside of BCM with a few exceptions noted below. If non-sensitive information is shared with outside institution collaborators, data will be identified before transmission and sent via secure email or via BCM's Microsoft OneDrive. The only exceptions are sharing addresses through OneDrive with Co-I Ramphul for geocoding and if we get audio-recorded interviews transcribed by medical transcriptionists - we make every effort to not use patient names in the interviews, but occasionally the participant will disclose their name or other PHI in the audio-recorded interviews.

We will be collaborating with the BCM Young Adult Diabetes Clinic, which is led by Siripoom McKay, MD who is a collaborator on this protocol. The Young Adult clinic will assist in the recruitment of Peer Mentors by posting the attached flyer (Section R) in their clinic, discussing the study with clinic patients both in person and by email, and sharing with the study team phone numbers/contact information for young adult patients who have expressed to Dr. McKay (or her affiliates at the clinic) an interest in learning more about becoming a Peer Mentor (and have verbally agreed to have their contact information shard for this purpose). Staff at the BCM Young Adult clinic will also notify study staff when they receive a referral for transfer of care from TCH Diabetes Care Center through the TCH electronic medical record (EPIC), to facilitate potential recruitment for the study.

Additionally, we will obtain releases of information to request medical chart data about study participants from any adult care providers they see for diabetes care during their time in our study, as detailed below. To protect confidentiality, all patient information the BCM Young Adult Clinic shares with our study team will be via secure email, BCM's Microsoft OneDrive, or via EPIC InBasket.

Will you obtain a Certificate of Confidentiality (COC) for this study?

Yes

Please further discuss any potential confidentiality issues related to this study.

We will obtain releases of information to request medical and appointment data from adult care providers. We will ask participants, at enrollment, to provide the names and contact information for family or friends who may help us locate the participants at follow-up if we are unable to make contact then.

Will information about the subject's participation be included in subject's medical records?

Yes

Please further discuss any potential confidentiality issues related to this study.

Participation is recorded in EPIC research tab

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There are no clinical billable procedures in this study. The two Hemoglobin A1c assay home collections will be processed and analyzed by Dr. Devaraj (a collaborator on this protocol) in her research lab, and all costs will be billed directly to the study. Neither the participant nor the participant's insurance company will be responsible for the costs.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

250

Distribution Plan:

YOUNG ADULT PARTICIPANTS: To promote completion of measures at all assessment points, we will use an elastic incentive program which increases the longer participants remain in the trial. Participants will receive $40 for completing baseline questionnaires and $25 for returning a completed home A1c kit (If no home kit is required the $25 for the A1c will be provided upon completion of baseline questionnaires), $60 for completing 6 month questionnaires, $75 for completing questionnaires at 12 months and $25 for returning the home A1c kit at 12 months. Additionally, participants will receive up to $15 for parking cost if we meet with them in person during recruitment, and $10 to share study experiences via an interview at the end of the study (subset of participants).

(continued in Section S attachments, "Section L" and "Section L Supplement Activities 4.13.22")

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

SAMPLE: Blood

What is the purpose of the sample collection?

The small blood sample will be used to run a Hemoglobin A1c assay. The Hemoglobin A1c assay will be used to asses glycemic control among young adult participants in this study. A home Hemoglobin A1c kit will be mailed to each young adult participant at baseline and 12 months. The kit will have all necessary supplies, instructions, and a self addressed prepaid mailer to return to study staff.

For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subjects entire participation time.

The home A1c kit tests only require a few drops of blood. The blood is collected by pricking the finger with a lancet. This will be collected for study purposes twice throughout participation.

Is there the possibility that cell lines will be developed with this sample?No

Sample will be obtained from:

Other: Young Adult participants

Will the sample be stripped of identifiers?

Yes

If sample will be released outside the hospital:

Will sample be released to anyone not listed as an investigator on the protocol? Will the information be identifiable, coded or de-identified?
N/A

Will sample material be sold or transferred to any third parties? Will the information be de-identified?
N/A

If sample will be banked for future use:

Where will the sample be banked and for how long?
N/A

Does the banking institution have an approved policy for the distribution of samples?
N/A

If the entire sample will NOT be used during the course of this research study:

Will the remaining tissue be discarded? If not what will be done with the remaining sample after study completion and how long will the sample be kept?
N/A

Will samples be made available to the research subject (or his/her medical doctor) for other testing?
No

If a subject withdraws from the study:

Will subject have the option to get the remaining portion of their sample back?
No

Will samples be destroyed? If not, will they be kept anonymously? What will happen to the sample if the subject revokes authorization?
The few drops of blood collected will be used to run the Hemoglobin A1c test, so there will be no blood sample left to destroy.

Will data obtained from their sample be deleted? What will happen to the sample if the subject revokes authorization?
The only data obtained from the small blood sample will be the Hemoglobin A1c. If the subject revokes authorization, the data will be deleted.

Will study data or test results be recorded in the subject's medical records?
Yes

Will results of specific tests and/or results of the overall study be revealed to the research subject and or his/her doctor?
Hemoglobin A1c results will be available to the participant, medical study collaborators, and their treating diabetes care providers at TCH. A summary of overall study results will be mailed to participants after the study is complete (no individual level data will be sent).

Please identify all third parties, including the subject's physician, to receive the test results.
Physicians will have access to Hemoglobin A1c results through the TCH electronic medical record (EPIC).

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance(other than food) that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)
No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Bulletin Board

Exact language of Advertisement:
HELP YOUNG ADULTS WITH DIABETES BE DIA-BETTER TOGETHER!

WHY PARTICIPATE: Managing type 1 diabetes as a young adult can be complicated, and many young adults have trouble after they leave pediatric care. We are inviting you to help support young adults during the transition from pediatric to adult care by getting trained to be a Peer Mentor! AIM: The DiaBetter Together Study is testing whether a strengths-based Peer Mentor program can help young adults as they transition from pediatric to adult care. BEING A PEER MENTOR INVOLVES: Mentoring other young adults with type 1 diabetes Getting trained by our study staff to be a Peer Mentor and staff will provide assistance along the way Completing questionnaires about your own experiences with diabetes and with being a Peer Mentor in our program

COMPENSATION: Peer mentors will receive money in appreciation of their time and efforts!

YOU MAY BE A PEER MENTOR IF YOU:

¿Ï Are between 20-35 years old

¿Ï Were diagnosed with type 1 diabetes before age 18

¿Ï Have had type 1 diabetes for at least 1 year

¿Ï Were receiving diabetes care in a pediatric setting and are now receiving care in an adult setting

TO LEARN MORE, PLEASE CONTACT:

{INSERT STUDY CONTACT INFO}

Principal Investigator: Marisa Hilliard, PhD

FOR YOUNG ADULT PARTICIPANTS: DIABETTER TOGETHER A Study for Young Adults with Type 1 Diabetes During the Transition to Adult Care What is the study about? » We are testing a strengths based peer support program to help with the transition from pediatric to adult diabetes care » For young adults (ages 17-25) with type 1 diabetes as they are leaving Texas Children¿s Hospital What does participation look like? » Filling out questionnaires 3 times over 1 year » Completing a home A1c kit twice over 1 year » Earning up to $235 over the course of the year You¿ll have a 50-50 chance of receiving the Peer Mentor program, which includes: » Connecting with a trained Peer Mentor who also has type 1 diabetes and is in adult diabetes healthcare » Receiving personalized support and guidance to help you manage diabetes as a young adult If interested, please contact the study team at: » Email: diabettertogether@bcm.edu » Phone: (832) 377-5620

Mode of Advertising: Other: Twitter

Exact language of Advertisement:

Example Twitter Advertisement language for advisory board Tweet 1: Looking for young adults w/ type 1 #diabetes to serve on Advisory Board for behavioral research lab at @TexasChildrens @BCMHouston. Will offer $ as thanks for your time and help! DM @mhill226 or call 832-824-7209 for details Threaded Tweet 2: Please note, replies are not private, please do not post identifying information ¿ DM me at @mhill226 or call 832-824-7209 if you are interested in learning more. Thank you!

Example Twitter Advertisement for peer mentors TWEET 1: The DiaBetter Together study @TexasChildrens @BCMHouston is looking for adults w/ #T1D (ages 20-35) who have transitioned from pediatric to adult T1D care & are interested in serving as Peer Mentors to provide support & guidance for young adults currently shifting to adult care.

TWEET 2: You will connect with young adults over a 12 mth period & be trained on how to offer support along the way. Offering $ as thanks for your time and & help! DM @mhill226 or call 832-824-7209 for info. Please note, replies are not private, please do not post identifying information.

Option B Tweet 1: Are you an adult w/ #T1D (age 20-35) who has transitioned from pediatric to adult #diabetes care? The DiaBetter Together study @TexasChildrens @BCMHouston is looking for Peer Mentors to help young adults w/ T1D currently making the shift to adult care. Tweet 2: You will be trained to offer support to young adults & connect with them for 12 mths. You will receive $ as a thank you for your time & help! Interested? DM @mhill226 or call 832-824-7209. Please note, replies are not private, do not post identifying information.

Option C Tweet 1: Are you an adult w/ #T1D (age 20-35) who has shifted from pediatric to adult diabetes care? Do you want to help other young adults w/ T1D going through the shift to adult care? The DiaBetter Together study @TexasChildrens @BCMHouston is looking for Peer Mentors to do just that! Tweet 2: You'll be trained to offer support & guidance to young adults & connect with them for 12 mths. You will receive $ as a thank you for your time & help! Interested? DM @mhill226 or call 832-824-7209. Please note, replies are not private, do not post identifying info.