Improving Diabetes Health in Emerging Adulthood Through an Autonomy Supportive Intervention

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Study Protocol with Statistical Analysis Plan

Protocol Summary

In Phase 1, we will invite 30 members of the target population to review and provide feedback on the three intervention components (10 beta testers will review one of the three components). Research assistants first obtain informed consent/assent from the participants (and their caregiver if the participant is <18 years old). They will then conduct a semi-structure interview with the youth that includes a presentation of one of the intervention components and a solicitation of feedback on the intervention. Youth will not be randomized; rather, research staff will begin contacting youth and sequentially enrolling interested youth who meet the eligibility criteria into Phase 1. Youth will participate in a one-time interview conducted either face-to-face or by video conferencing scheduled at a time that is convenient for the youth. We will conduct face-to-face interviews either in the youth's home or in the Clinical Research Center located within the Integrated Biosciences (IBio) Building on the Wayne State University main campus. Interviews will be audio-recorded and transcribed for analysis. Any video recordings generated by the video conferencing software will be deleted and only the audio component of the recording retained for transcription. The intervention components will be refined based on this feedback.

In Phase 2, we will enroll 320 youth into a component selection experiment the goal of which is to test the efficacy of the intervention components. We will recruit participants from three outpatient hospital clinics (Children's Hospital of Michigan, Detroit Receiving Hospital's University Health Center, and Henry Ford Hospital, and from the WSU community by advertising the research study on Academica. Prior to randomization, we will conduct a beta test with up to 10 participants to ensure the remote study visit and intervention procedures are functioning correctly. Beta testers will not be randomly assigned, rather, the PI will assign them to one of the study arms in which intervention components are delivered. Youth will be enrolled into the study one month prior to an upcoming diabetes clinic visit. Youth will be enrolled for six months during which they will complete three study visits: baseline, two-, and six-month post-baseline. Prior to study entry, research staff will obtain informed consent/assent from participants and the caregivers of youth <18 years old. To facilitate remote study visits, informed consent/assent will be collected via electronic signature on RedCap. Research staff will administer questionnaires via a HIPPA-compliant electronic data capture system (REDCap), download the youth's blood glucose meter, facilitate the collection of a small sample of blood via fingerstick for the assessment of HbA1c using the Accubase A1c home test kit, assist the youth in downloading the intervention software application (app) onto their preferred mobile device, and review the youth's medical record for diabetes illness characteristics (e.g., date of diagnosis, treatment regimen). For participants that live more than 30-miles of the WSU campus, HbA1c kits and completion instructions will be mailed to their homes; RAs will still facilitate the blood collection. Participants will have the option to mail their own A1c home test kits. The mailed test kits will be monitored via a tracking number to ensure they have been sent. Blood glucose meter data may also be downloaded over a telephone call or via video conference. The study statistician/data analyst will randomize youth to one of eight intervention conditions using a 1:1 ratio and stratifying based on HbA1c (10.5% cut point). Youth randomized to arms 1-3 will receive one intervention component, either the QPL, MES, or TXT. Youth randomized to arms 4-6 will receive two intervention components, the QPL+MES, QPL+TXT, or MES+TXT. Youth randomized to arm 7 will receive all three intervention components and those assigned to arm 8 will receive treatment as usual (standard care control). The intervention coordinator will notify

youth of their treatment assignment and launch them on their assigned intervention components. All interventions will be delivered using the CIAS software package (Interva, Inc.). Participants will access MES and QPL via a link sent to their mobile device. Youth randomized to MES will receive two eHealth intervention sessions; the link to the first will be sent within one week of the baseline data collection, the second will automatically be sent 30 days after they complete session 1. The link to complete the QPL will be delivered two weeks prior to the youth's diabetes clinic visit. Upon completion, the Intervention Coordinator will forward the QPL report (i.e., list of questions/ conversational prompts selected by the youth) to the youth prior to their clinic visit (CIAS does not yet allow for direct delivery to the participant). In TXT, youth will receive 30 days of twice daily one-way text message reminders. Youth will determine the timing of messages and area of diabetes care for which they will receive reminders – blood glucose monitoring, insulin administration, carbohydrate counting, or all three areas. All participants will continue to receive standard medical care from their usual diabetes medical care provider. The post-intervention assessments will occur 2 months post-baseline (T2; timed to occur one month after the completion of MES session 2, the TXT component, and the diabetes clinic visit at which the participant would have used the QPL) and 6 months post-baseline. The T2 & T3 visits will include completing research surveys via REDCap, measuring the youths' HbA1c using a home test kit, and downloading data from the youths' blood glucose meter. All data collection sessions will take place either face-to-face at the clinic research space at Wayne State University iBio/Clinical Research Center, in a private place of the participant's choosing (i.e., their home or library meeting room), or via video conferencing software. Youths will be compensated with a $100 gift card per completed study visit, for a total of up to $150 dollars. If the youth is assigned to the MES (2 sessions) or QPL component, they will be compensated with a $5 gift card per study component, for up to $15. If the youth mails their A1c home test kit, they will be compensated with a $10 gift card.

We will initially characterize data heterogeneity and document the distributions of HbA_{1c}, the primary outcome, and all secondary/exploratory outcomes (diabetes management and treatment attendance). We will check for out-of-range values, outliers and abnormal values using graphical methods (e.g., boxplots and histograms) and create descriptive summaries to ensure that all values are within expected ranges. Unexpected findings will prompt checking of raw data for accuracy of data entry and recording. We will analyze the effect of the intervention components on the longitudinal measures of HbA_{1c} using the mixed effects linear model for the ANOVA of a factorial design. This model will include a fixed effects indicator for each intervention component (QPL, MES, TXT) and time along with all interactions with time. Random intercepts will be used to account for the longitudinal nature of the data. Before evaluating which components contribute to a potential reduction in HbA_{1c}, we will use the model to compare the treatment with all three components and the control treatment to determine whether the complete intervention was efficacious. If this statistical test is significant, we will identify those components that result in a significant reduction of HbA_{1c} by examining the interactions between the main effects and time beginning with the simplest effects and only adding higher-order interactions if needed. We will use $\alpha = 0.05$ for the test of total effect (difference between the treatment with all 3 components and the control treatment) and $\alpha = 0.1$ to identify which components contribute to the total effect. We will use a higher α for the component selection test because we want to reduce the likelihood of not selecting a component that is contributing to the total effect. Secondary/exploratory outcomes (diabetes management and treatment attendance)

will be analyzed using a similar approach but are not powered. Since the treatment attendance outcome is not continuous, a generalized linear model will be employed.