Study title: Does a Behavior Change Skills and Physical Activity Program Improve Self-regulation and Health Outcomes in Adolescents with Type 1 Diabetes?

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PROTOCOL SUMMARY

Project Title: Does a Behavior Change Skills and Physical Activity Program Improve Self-regulation and Health Outcomes in Adolescents with Type 1 Diabetes?

Protocol Version Date: **February 16, 2023**

Principal Investigator: Amy Hughes Lansing, Ph.D.

Check the type of the review:

[ ] Full convened meeting - The IRBs employ the convened meeting review process for review and approval of studies that are more than minimal risk.

[X] Expedited review - The IRBs employ the expedited review process for approval of studies that are determined to be minimal risk and only involves activities such as; prospective collection of biological specimens for research purposes by noninvasive means (blood collection, salvia, nail clippings), collection of data through noninvasive procedures (ultrasounds, MRI, physical sensors) and research on behavior such as perception, cognition, motivation, identity, language and communication.

PURPOSE AND OBJECTIVES

Purpose: The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information.

Adolescents with type 1 diabetes and socioeconomic disadvantage (SED) experience significant health disparities in glycemic outcomes in adolescence and cardiovascular disease and diabetes-related death later in adulthood.[1,2] SED is associated with elevated glycated hemoglobin (HbA1c) and 3x risk of repeat hospitalizations for diabetic ketoacidosis as well as 2-3x risk of cardiovascular disease and diabetes-related death. Suboptimal glycemic outcomes are a powerful determinant of long-term health complications and costs,[3,4] with a 1% reduction in HbA1c contributing to up to a 40%[1,2] reduction in risk for later nephropathy, retinopathy, and macrovascular disease. Given the substantial health disparities for persons with type 1 diabetes and SED and the many challenges that adolescents face with achieving optimal glycemic levels (<20% nationally meet American Diabetes Association HbA1c targets), this is a critical population to support in health behavior change via psychosocial intervention during adolescence. Unfortunately, existing evidence-based psychosocial type 1 diabetes interventions for adolescents, including robust multi-system approaches, have demonstrated limited efficacy for behavior change that results in improved glycemic outcomes and none have directly targeted cardiovascular health outside of glycemic outcomes.[5–8] In this project, we pursue a new avenue for intervention innovation by testing a nationally-scalable diabetes behavior-change skills training and physical activity intervention program to improve glycemic outcomes and decrease cardiovascular disease risks for adolescents with type 1 diabetes and SED.

Scientific Premise

The proposed work is based upon biobehavioral models of self-regulation and diabetes pathophysiology that identify disrupted self-regulation systems (behavior, emotion, and physiological) as critical to explaining suboptimal glycemic outcomes and point to behavior skills training combined with physical activity as a promising evidenced-based approach to ameliorate self-regulation deficits and improve glycemic and cardiovascular outcomes in adolescents with type 1 diabetes and SED.

a) Disrupted biobehavioral self-regulation systems contribute to suboptimal glycemic outcomes in adolescents with type 1 diabetes.

Engaging in optimal diabetes treatment self-management is a tremendous challenge encompassing some 600+ tasks and upwards of 4-5 hours of time in the day.[10,11] The majority of adolescents with type 1 diabetes report regularly experiencing heightened stress from managing their disease and that stress is associated with suboptimal diabetes outcomes.[12] Heightened stress affects type 1 diabetes both *indirectly* through decreased engagement in disease management behaviors and *directly* through the effects of physiological arousal, hormone secretion, and insulin resistance on blood glucose levels and the vascular system.[13] Sustaining the complex behavior change required for optimal diabetes self-management necessitates robust biobehavioral self-regulation systems for the modulation of behavior, distress, and stress physiology.[14]

Prior research by our team has established that biobehavioral self-regulation systems are foundational for diabetes self-management including building skills that support diabetes-related behavior change and optimal glycemic outcomes.[15] For example, this work has confirmed the importance of behavior and distress regulation for adolescent

diabetes management and glycemic outcomes as assessed via neuropsychological test batteries and patient/parent-reported measures.[1617,18] Our research further shows that behavioral and distress regulatory systems interact in explaining daily blood glucose levels for adolescents with type 1 diabetes.[19] In addition, our team's research has identified key reward processing mechanisms in adolescents with type 1 diabetes, delay discounting and attentional bias to diabetes cues, that are associated with both disease management and glycemic outcomes in adolescents and emerging adults with type 1 diabetes.[16,20,21]

b) Biobehavioral self-regulation systems are interconnected with inflammation and cardiovascular disease processes.

Type 1 diabetes is a pro-inflammatory disease associated with elevated systemic and neuroinflammation.[22–24] Systemic and neuroinflammation related to diabetes pathophysiology, including diabetic ketoacidosis (2-3x more likely with SED), contributes to deficits in neural function, including neural systems that support behavior and distress regulation, and contributes to atherosclerosis and endothelial dysfunction which accelerate the progression of cardiovascular disease.[25–27] Adolescents with SED are at greater risk for experiencing impaired self-regulation and elevated inflammation as well as cardiovascular disease.[28–30] For example, youths with type 1 diabetes and SED compared to those without SED experience elevated inflammation (c-reactive protein) that is linked with elevated HbA1c. For adolescents with type 1 diabetes and SED, experiencing impairments in biobehavioral self-regulation systems in the context of a pro-inflammatory disease may drive a cycle of persistent suboptimal glycemic levels and impaired self-regulation that hinders behavior change and amplifies risk for long-term cardiovascular disease.[31,32] Enhancing biobehavioral self-regulation systems may be critical to improving glycemic outcomes and preventing cardiovascular disease.

c) Directly targeting cardiovascular disease risk beyond glycemic outcomes is critical for reducing health disparities in persons with type 1 diabetes.

Elevated glycemic levels are a primary predictor of later cardiovascular disease risk for adolescents with type 1 diabetes, with even a period of suboptimal glycemic levels contributing to persistent increases in later cardiovascular disease risk.[33] Yet, for those with type 1 diabetes and SED improvements in diabetes-self-management and glycemic outcomes alone do not entirely resolve health disparities in cardiovascular disease. This may be due to both increased prevalence of conventional cardiovascular disease risk-factors and type 1 diabetes-specific risk processes. First, adolescents with type 1 diabetes show early elevations in known cardiovascular risk factors, with 38% evidencing elevated low-density lipoprotein-cholesterol levels, 22% evidencing elevated blood pressure, and 39% evidencing overweight or obesity,[23] with increased rates of these risks present in adolescents with SED.[34,35] In adults with type 1 diabetes, targeting conventional cardiovascular disease risk-factors, beyond glycemic levels, contributes to perhaps a 29% reduction in risk of death;[36] however, these risk factors are not typically assessed nor targeted in intervention programs for adolescents with type 1 diabetes. Additional risks for cardiovascular disease may be unique in persons with type 1 diabetes. For example, in adolescents with type 1 diabetes, combined elevations in high density lipoprotein and systemic inflammation together predict early progression of cardiovascular disease, such that inflammation is argued to disrupt the anti-inflammatory function of high density lipoprotein.[37] Interventions that specifically target both conventional cardiovascular risks and systemic inflammation might have increased potency for cardiovascular disease prevention in adolescents with type 1 diabetes and SED.

d) Physical activity promoting interventions combined with diabetes behavior-change skills training might be particularly potent for targeting self-regulation, glycemic levels, and cardiovascular disease risk.

Existing studies provide support for the efficacy of individual[38–42] and family-psychosocial diabetes interventions in adolescence. However, these treatments show only small to moderate effect sizes (ES = 0.13-0.35)[43,44] with mean HbA1c remaining >8.5%[6,45], and gains often lasting less than 6 months. Moreover, these interventions often require specialized mental health providers or multi-component services that are not scalable or widely available to families with SED, and these interventions have yet to specifically target traditional cardiovascular disease risk factors. Combining an evidence-based diabetes behavior-change skills training program with a physical activity promoting intervention might be both a potent and scalable means to increase self-regulation, improve glycemic levels, and decrease cardiovascular disease risks in adolescents with type 1 diabetes and SED.

More specifically, diabetes behavior-change skills training programs can be readily delivered in highly scalable, online formats; however, alone, lack the potency to drive enough improvement in HbA1c. Physical activity promoting interventions are also scalable, and have been shown to benefit biobehavioral self-regulation systems, which may

amplify the impact of diabetes behavior-change skills training, as well as glycemic outcomes and cardiovascular risks. For example, increased weekly engagement in moderate to vigorous physical activity is associated with enhanced self-regulation, including for behavior, distress, and inflammation.[46,47] Benefits from physical activity interventions on behavior regulation appear after as little as six weeks of intervention.[48] Emerging evidence supports that increased physical activity might also benefit glucose regulation in youths with type 1 diabetes.[49] Moreover, physical activity is a known potent intervention to reduce cardiovascular risk, including increased insulin sensitivity, increased high-density lipoprotein, lower triglycerides, lower c-reactive protein and improved vascular function.[50,51] Yet, despite this evidence base, a scalable, combined diabetes behavior-change skills training and physical activity promotion intervention has not been tested to reduce health disparities among adolescents with type 1 diabetes and SED.

Expected Impacts of the Proposed Work

We have previously developed and pilot-tested the components of a scalable diabetes behavior-change skills training and physical activity intervention for adolescents with type 1 diabetes and SED.[8,52] In this proposal, we will test the benefits of this evidence-based program on self-regulation, glycemic outcomes and cardiovascular disease risk. This program has the potential to yield decreases in long term disparities in diabetes-related complications and death and has the potential for adoption nationally resulting in reduced health disparities for persons with type 1 diabetes and SED.

References. Include references to prior human or animal research and references that are relevant to the design and conduct of the study.

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Objectives: Clearly state the primary and secondary objective(s) of the study.

Aim 1. Assess the acceptability and proximal benefits of the Activate program for adolescents with type 1 diabetes and SED
We will conduct a two-arm randomized trial with 60 adolescents with type 1 diabetes, with and without SED, comparing the 12-week Activate program to a treatment-as-usual control group.

Aim 1a: To assess acceptability of the Activate program we will examine participant engagement with the Activate program components, including diabetes behavior-change skills training sessions completed and physical activity goals met, as well as qualitative and quantitative participant feedback on their experience with the program at the end of treatment. *Aim 1b:* To assess the preliminary efficacy of the Activate program we will examine changes in proximal outcomes of behavior-change skills (goal setting, problem-solving, and coping skills), and active minutes compared between treatment and control groups from baseline to a 12-week follow-up assessment. We will assess behavior change skills via self-report and active minutes as minutes of moderate to vigorous physical activity via a Garmin fitness activity tracker.

Aim 2. Explore the impact of the Activate program on secondary mechanisms and outcomes linked with longer-term type 1 diabetes health disparities. To assess the efficacy of the Activate program on secondary mechanisms and outcomes we will examine changes in adolescent self-regulation of diabetes behavior, distress, and inflammation as well as glycemic outcomes and cardiovascular disease risks between treatment and control groups from baseline to the 12-week follow-up. We will assess diabetes behavior and distress through self-report measures. We will also assess inflammation (c-reactive protein), glycemic outcomes (glycated hemoglobin-HbA1c), and additional cardiovascular risks (American Heart Association Life's Simple Seven risk index).

METHODS AND PROCEDURES

Study Design: Describe the research design, including a description of any new methodology and its advantage over existing methodologies.

This project is comprised of a two-arm randomized control trial (RCT) testing the feasibility, acceptability, and preliminary efficacy of a nationally scalable program, *Activate*, a 12-week, technology-delivered diabetes behavior-change skills training and physical activity promotion program for adolescents with type 1 diabetes and SED. First, in the two-arm RCT with 60 adolescents with type 1 diabetes, we will compare the 12-week Activate program to a treatment as usual control group on proximal outcomes of behavior-change skills and daily active minutes. Second, we will test the impact of the Activate program on secondary mechanisms and outcomes linked with later type 1 diabetes health disparities: adolescent diabetes behavior regulation, psychological distress, inflammation, glycemic outcomes, and cardiovascular disease risk.

Conceptual Innovation: Psychosocial interventions for adolescents with type 1 diabetes and SED have not directly targeted biobehavioral self-regulation systems across behavior, distress, and physiology/inflammation regulation nor directly targeted cardiometabolic health outside of improvements in glycemic outcomes. Our proposed work will pursue a new avenue for reducing diabetes health disparities by enhancing adolescent biobehavioral self-regulation systems and directly targeting cardiovascular health through an evidence-based diabetes behavior-change skills training and physical activity promotion program.

Methodological Innovation: Psychosocial type 1 diabetes interventions for adolescents have primarily focused on pediatric endocrinology clinic and psychology clinic delivered interventions that require substantial patient time commitments and specialty trained mental health providers, which has limited the scale of distribution and reach for these interventions. Our proposed work will utilize a mixed clinic-based and online national recruitment system that leverages social media and online platforms to recruit a nationally representative sample to participate in our scalable web and text-delivered program. Using this national recruitment method, our research team has successfully recruited, in only 28 days, 209 youths with type 1 diabetes from 43 states to participate in virtual surveys and tasks with over 81% of those youth indicating willingness to participate in an online intervention program.[21] Direct-to-patient recruitment is a novel way to directly engage patients in interventions via the web,[53–57] and allows the testing of health programs with the potential for national scaling and access.

Procedures: Describe all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc.

Note: A clinical research protocol may involve interventions that are strictly experimental or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified.

All procedures will be conducted solely for research purposes. We will recruit 60 adolescents aged 13-17 years old with type 1 diabetes, through pediatric endocrinology clinics and via a national advertising recruitment method established with our research team that leverages Facebook, Instagram, and Google Ads resulting in a nationally representative sample. National advertising recruitment: Interested families will contact the research team. Pediatric endocrinology clinic recruitment: A clinic staff member will provide the same online information used in national recruitment about the study to the family during a clinic visit and interested families will be provided with instructions for how they can contact the research team if interested in participating. At the University of Vermont Medical Center pediatric endocrinology clinic, a member of the patient's care team will ask eligible families for permission to have one of our research team members enter to share our same recruitment flyer used in national recruitment about the study and instructions for how they can contact the research team if interested. Research staff will respond to interested families and explain the study procedures in greater detail to the adolescent and to the adolescent's legal guardian. If both agree, the research assistant will arrange for a call to complete the electronic informed consent and assent process through RedCap. After consent/assent, the adolescent and parent will complete the baseline video-based lab assessment and be mailed an assessment kit with all required tools for the assessment and program (dried blood spot assays, Garmin fitness activity tracker, measuring tape, electronic blood pressure cuff, scale). Families without a computer, tablet, or phone, will be provided a small tablet to use for assessments.

The baseline assessment will be conducted with the ongoing support of the research staff via a video conference using Larner College of Medicine Zoom with HIPAA-compliant settings and the parent available at home. There will be no video recording. First, the adolescent and parent will complete a set of online questionnaires (through RedCap), see descriptions below of measures. Second, the adolescent will complete the physical assessments:

Dried Blood Spot Assay: A mail-in dried blood spot assay for cardiometabolic risk factors will be collected (Kapur ZRT Laboratory, 2008). Kits for blood spot collection contain a filter paper collection card, finger lancets, an alcohol prep pad, sterile gauze, a band-aid, easy-to-follow instructions, and a mailer to return the sample for analysis. The test kit will be included in the mailed assessment kit and adolescents will follow the instructions provided in the test kit with research assistant support for any questions. The test kit instructions will ask participants to provide a finger-stick blood sample on a collection card and to mail the dried blood sample (at least 3 hours dried) coded to the lab for storage before bulk processing at ZRT Laboratory. Please note that these test kits are commonly used by patients with diabetes and involve procedures that are similar to blood glucose monitoring that patients complete multiple times each day. Dried blood spot samples are also stable at room temperature for up to 1 month and dried blood spots are exempt from biohazard mailing regulations as with triple-packaging as provided in test kit there is no reasonable expectation of occupational exposure to blood (CDC, 2017). This procedure allows us to collect information about cardiometabolic risk factors from the

participants at home using a highly familiar finger stick blood test. We have successfully used this method of home testing in youths with type 1 diabetes in prior studies.[84]

Abdominal Circumference: The assessment kit will include a measuring tape and instructions for measuring abdominal circumference at the midpoint between the bottom of the rib cage and the iliac crest and at the hip. Participants will be trained and then asked measure the abdominal circumference. The participant will report and confirm on the measuring device the measurement to the research assistant.

Blood pressure: The assessment kit will include an electronic blood pressure cuff and the research assistant will provide instructions to place the cuff 1 inch above elbow with arm relaxed before starting the measurement. The participant will report and confirm on the measuring device the blood pressure to the research assistant.

Weight: The assessment kit will include a small digital scale and the research assistant will provide instructions for use. The participant will report and confirm on the scale the weight to the research assistant.

Glucose meter and insulin rate reporting: The research assistant will provide instructions for the participant to report readings from their diabetes devices. For continuous glucose sensor and insulin pump users, device data for the past month will be provided through data exports from the device software for sharing with healthcare teams, with no medical device ID or personal identifiers retained. For glucose meter users, they will report glucose readings for the last 7 days from their glucose meter. For insulin injection users, they will report long-acting insulin doses and carbohydrate exchange ratios used over the last 7 days.

As the final activity of the baseline assessment, the participants will be randomized to the Activate program or treatment-as-usual and receive instruction, if required on completing the intervention program, and for all the follow-up assessment.

After twelve weeks, adolescents and their primary caregiver will repeat the entire baseline assessment battery in a second video-based lab appointment. Adolescents will receive $25 for the intake assessment and $50 for the follow-up assessment on a study provided cash card or gift card. Adolescents will return the assessment toolkit with a pre-paid mailing label.

Intervention: Activate Program
Adolescents randomized to the active condition will participate in a 12-week online diabetes behavior-change skills training and physical activity promotion program. See attached intervention guide for protocols beyond description below.

Diabetes Behavior-Change Skills Training. Behavior-change skills training will be provided through eight web-delivered content and activity sessions across the 12-week program. Sessions 1 through 4 will occur weekly and sessions 5 through 8 biweekly. Each session takes approximately 15-20 minutes for the adolescent to complete both content learning and related activities. Session 1 (week 1 of program) provides an introduction to the entire Activate Program as well as a goal-setting activity related to type 1 diabetes management. Sessions 2-8 (weeks 2 to 12 of the program) provide physical activity reminders that overlap with text-based support for the physical activity program (see below) as well as specific session content for behavior-change skills training: goal setting, goal planning and rewards, identifying challenges, problem-solving, increasing social support and positive activities, and managing strong emotions.

Physical Activity Incentives Program. The physical activity incentives program includes 12 weeks of personalized goals and incentives for increasing physically active minutes along with weekday text-based support. Active minutes, defined as minutes with moderate to vigorous physical activity, will be tracked via a Garmin fitness activity tracker, which is synced to a coded study-specific account via PhysioQ's Labfront, a secure site used to collect and manage Garmin fitness activity tracker data. All data will be deidentified and only accessible to the research team. In week 1, all adolescents will receive incentives for syncing their Garmin fitness activity tracker on at least five days. In weeks 2 to 12, adolescents will receive personalized daily and weekly activity goals based on their progress. Daily incentives will be offered for meeting daily goals, and increased earnings will be available for meeting weekly bonus goals. Maximum earnings across the 12 weeks will be $430. Weekdays, text-based support will be provided to remind adolescents of goals and earning potential as well as additional support to problem-solve technology and physical activity difficulties when indicated. Education prior to the intervention will follow American Diabetes Association[31] guidance including information about how insulin requirements change with increased physical activity and how to prevent hypo and

hyperglycemia during and after exercise as well as reviewing the adolescent's plans for managing low blood glucose and contacting their pediatric endocrinologist with questions about glucose management with increased physical activity. All incentives will be delivered weekly on a cash card provided by the study or via gift card(s) provided at an interval chosen by the participant.

Treatment-as-Usual Control condition. For those in treatment as usual, participants will be trained to wear a Garmin fitness activity tracker daily for the next 12 weeks and asked to follow their standard care for diabetes management.

Describe required screening procedures performed before enrollment and while on study.

Contact between potential participants and study personnel will be initiated by the potential participants and their caregivers. Potential participants and their caregivers will respond to internet or clinic-provided advertisements and will be routed to our study website. Our study website will contain a description of study procedures and link to request contact regarding study participation. A research assistant will return contact with interested families to answer questions about the study and confirm eligibility using the screening consent script and set a date/time for consent/assent. Inclusion criteria will be the adolescents aged 13-17, and not turning 18 during study participation, with type 1 diabetes, being at least 18 months post-diagnosis, parent reported moderate to no physical activity for adolescent, ability to complete measures and intervention program in English, and access to broadband or cellular internet and currently residing in and receiving healthcare in the United States. After 30 participants are consented and enrolled into the study, we will add the following inclusion criteria: adolescent is from a marginalized racial or ethnic group. Exclusion criteria will be ward of state, active psychosis, and/or severe medical or psychiatric illness that limit participation including participation in physical activity. Participants will be provided contact information for the PI and lab to communicate during the 12-week study period about any concerns for eligibility (e.g., loss of internet, change in legal guardian status) and the PI will evaluate continued participation based on confirmation of meeting eligibility requirements.

For research involving survey, questionnaires, etc.: Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation.

☐ **Not applicable**

Each assessment will be scheduled for a three-hour window to complete the questionnaires (80 minutes), the physical assessments (dried blood spot, abdominal circumference, blood pressure, and diabetes device reporting; 40 minutes), and at intake introduction to the treatment condition (20 minutes). Each assessment appointment is anticipated to last 2.5-3 hours.

Primary Outcomes

Behavior-Change Skills. We will use two measures to assess key behavior-change skills taught in the intervention program: goal setting and coping skills. Adolescents' goal setting will be assessed using a procedure by Karoly et al. (2005) that was validated for use with adolescents with type 1 diabetes.[65,66] Participants will be asked to identify their most important diabetes, academic, social, and career/family goals. Following this, participants will be asked to identify which of their three non-diabetes goals most interfered with their diabetes goal. Participants will also complete the four-item planning subscale from the Goal System Assessment Battery[65] to determine goal-directed planning activity related to the diabetes goal identified in the goal assessment. Average levels of goal-directed planning will be used as the outcome variable for goal setting. Adolescents' coping skill self-efficacy will be assessed using the Coping Self-Efficacy Scale, a 26-item measure that indexes participants confidence in using different strategies to cope with challenges in daily life.[67]

Active minutes. We will use Garmin fitness activity tracker tracking to determine the average number of daily minutes with moderate to vigorous physical activity, metabolic equivalents (METs) greater than or equal to 3 METs, in week 1 and week 12.

Secondary Biobehavioral Self-Regulation Mechanisms

2. Self-Report Assessment of Behavior Regulation and Distress: The self-report tasks will be completed via questionnaires linked only to study ID on RedCap with the access link provided by the research assistant. When noted the parent will also report on their perception of their child's functioning in that domain.

Self-Regulation. We will use the following measures to assess regulation generally and in the diabetes context.

3. Diabetes Functional Assessment[29]: The Functional Assessment of Maladaptive Behaviors measure assesses perceptions of the extent to which a person's behavior was sensitive to particular reinforcers by rating eight statements regarding the function of the behavior on a 4-point scale. This measure is based on the four-function model of behavior reinforcement and will assess eight diabetes management task reinforcers following the stem "*To what extent did you complete diabetes management tasks to . . ."* with options of *"resolve symptoms of low or high blood glucose, resolve worry about diabetes, continue glucose in-range with few symptoms, feel good or proud, stop caregiver from nagging/reminding or worrying, avoid conflict or interaction with family or school nurse, get praise from caregiver or health professional, get attention from caregiver or peers."* The functional assessment tool has predicted suboptimal behavior regulation for a variety of health concerns including unhealthy eating behavior.
4. Diabetes Habit Strength (DHS)[37] which includes 16 items that measure perceived habitual responding for glucose checking, insulin dosing, and carbohydrate counting and predicts daily treatment engagement in adolescents with type 1 diabetes.
5. Self-care Inventory,[38] which includes 21 items that measure diabetes treatment engagement, which is associated with more optimal glycemic outcomes. Parents and adolescents will report on this measure.
6. Effortful Control Scale Short: Adolescents will report on 16 items that describe challenges with self-regulation including inhibitory control, attention, and activation control.
7. Delay Discounting: A 5-item tasks that assesses preference for immediate over delayed rewards.
8. Diet Regulation: 21 items that assess pro- and anti-inflammatory food intake from the NaSSDA diet questionnaire.
9. Diet and physical activity habit strength: which includes 14 items that measure perceived habitual responding for food and physical activity.
10. Food patterns and behavior: 4 items from the National Youth Physical Activity and Nutrition Study (NYPANS, 2010) that measure adolescent's eating behaviors. Questions 93 and 101-103 will be asked from this survey.
11. Diabetes nutrition literacy: The Type 1 Diabetes Nutrition Knowledge Survey (Rovner et al., 2012) measures understanding of nutrition information, assessing general nutrition literacy and diabetes-specific nutrition literacy. Parents and adolescents will report on this measure.
12. Home nutrition environment: Parents and adolescents will report on this measure. Parent reported nutrition environment will be measured using the Nutrition Environment Measures Survey (NEMS-P). Adolescent reported home nutrition environment will be measured using the NHANES Flexible Consumer Behavior Survey (NHANES FCBS).
13. School nutrition environment: 5 items from the School Nutrition Dietary Assessment (SNDA) (USDA Food and Nutrition Service) measure perceptions of school nutrition environment.
14. Social support for healthy eating: 2 items adapted from Sallis et al., (1987) measure adolescent perception of support from family and friends encouraging their eating habits.

Distress. We will use the following measures to assess distress generally and in the diabetes context.

15. Patient Health Questionnaire for Adolescents (PHQ-A)[36], including 8 items that index symptoms of depression (excluding item 9 for suicidal ideation). Adolescents with type 1 diabetes are at elevated risk for experiencing symptoms of depression that overlap with symptoms of diabetes distress.
16. Psychopathology via the Pediatric Symptom Checklist (PSC-17), including 17 items that index internalizing, externalizing, and attention symptoms in children. Parents will complete this measure.
17. Motivation and Energy Inventory (MEI)[35], which includes 26 items that measure the extent of diminished engagement in reward motivated cognition, physical behavior, and social interactions. Greater motivation and energy is associated with greater challenges with health behavior regulation.
18. Perceived Stress Scale (PSS) (Cohen & Williamson, 1988) is a widely used self-report measure of perceived stress with well-documented reliability and validity. Adolescents with high HbA1c report higher levels of general perceived stress.
19. Diabetes Stress Scale- Short Form (DSQ; Delameter et al., 2012) is an 24 item frequently used measure of diabetes-specific stressors in adolescence with strong reliability and validity as well as associations with

suboptimal diabetes self-management and glycemic levels. Parents and adolescents will report on this measure.

20. Type 1 Diabetes Quality of Life (T1DAL)[39], which includes 23 items that measure diabetes-related quality of life which is associated with treatment engagement and glycemic outcomes.

Secondary Health Outcomes

Inflammation. We will assess a primary marker of inflammation, c-reactive protein, through dried blood spot assay (see protocol above). Elevated c-reactive protein is associated with increased risk for atherosclerosis, endothelial dysfunction, and risk for cardiovascular disease.

Glycemic Outcomes. We will use the following measures to assess glycemic outcomes:

21. Glycated Hemoglobin (HbA1c) will be assessed through dried blood spot assay.
22. Mean Daily Blood Glucose (MBG) and Mean Variability in Blood glucose will be assessed by participant report from diabetes device data from glucose meters and CGMs. This will include data from the 7 days prior to the baseline assessment and 7 days prior to the follow-up assessment and will be used to index MBG and standard deviations in blood glucose levels (SDBG), both of which are available without requiring CGM. For those with CGM we will also examine time-in-range.
23. Insulin Resistance will be assessed by the estimated glucose disposal rate (eGDR) calculated from abdominal circumference and blood pressure measures at baseline and follow-up assessments (see protocol above).
24. Insulin Needs: Self-perceived insulin needs will be assessed using a single Likert scale question asking how the parent believes the teen's insulin needs have changed over the last 12 weeks (decreased greatly – increased greatly). This question will only be asked in the follow-up appointment after the 12 weeks. Parents will report on this measure.

Cardiovascular Disease Risk Score. We will assess per the American Heart Association Life's Simple 7 index, which includes weight, blood pressure, diet, physical activity, blood sugar, and cholesterol. We are excluding smoking which would not be anticipated to change in response to this intervention and has low base rates in adolescents with type 1 diabetes. Physical indicators will be assessed through the dried blood spot assay including total cholesterol and HbA1c. We will also assess weight, physical activity as well as systolic and diastolic blood pressure through our home-based virtual assessment protocol (see above). Last, we will ask the adolescent to report on diet habit using the standardized healthy diet questions from that match the American Health Association Healthy diet recommendations and they report if they tried or currently smoke. Cardiovascular health risks will be summarized through a single risk score. For each risk indicator, meeting ideal, intermediate, or poor health status will be associated with a score of 2 to 0, respectively, creating a 0 to 14 scale of cardiovascular disease risk.

TYPES OF PROCEDURES (Please do not use the "other" option unless the procedure is not listed.)
Check all that apply.

X	Survey (mail, telephone, in-person, on-line)	X	Blood drawing: dried blood spots from finger stick	Vol.	10 drops of blood (30µL)	Over days, weeks?	Across two assessments 12 weeks apart (5 drops/ 15µL/assessment)
X	Medical exams/history: blood pressure and abdominal circumference only					Type & Amt.	Dried blood spot card with 5 discs
	Deception ***see below**		Surgery				Collection of Urine and/or Feces
	Observation		Drug Administration				HIV Testing
	Photographs	X	Device Use: Garmin fitness activity tracker				Ultrasound (e.g. echocardiogram)
	Audio Recording		Exercise				Imaging (e.g. CT scan, DEXA, mammogram, PET scans, SPECT)
	Video Recording		Diet				Use of Radiation treatment
	Interviews in person or by		Pathology Specimens				Use of Radioactive substances (e.g.

☐	phone	☐	(retrospective)	☐	radiolabeled antibodies, drugs or contrasts)
☐	Focus Groups	☐	Genetic Materials (DNA)** **see below**	☐	MRI (for treatment studies)
☐	Review of prospective data	☐	Questionnaires	☐	MRI (not for treatment studies)
☐	Review of retrospective data	☐	Diaries	☐	Tissue (obtained for clinical purposes)
☐	Recording of Identifiable Data	☐	Pregnancy Tests	☐	Tissue (obtained solely for research)
☐	Electrocardiograms				
☐	Sensitive Data (criminal or sexual conduct, drug or alcohol conduct or use)	(specify):			

****If genetic information is being collected, GINA language must be added to the consent form.**
*Deception typically involves withholding information from the potential subject and would require an alteration to the consent process.

Statistical Considerations: Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible.

In aim 1, we assess the feasibility and acceptability of the Activate program as well as its preliminary efficacy on behavior-change skills (goal-setting and coping skill efficacy) and average daily active minutes. To assess acceptability of the Activate program we will examine participant engagement with the Activate program components, including behavior skill training sessions completed and physical activity goals met, as well as qualitative and quantitative participant feedback on their experience with the program at the end of treatment. A priori benchmarks for acceptability, indicating no further revision is needed will be greater than 80% of sessions completed and physical activity goals met as well as more than 80% of participants providing positive feedback regarding willingness to participate again.

To assess the preliminary efficacy of the Activate program we will examine changes in proximal primary outcomes of goal-setting, coping skill efficacy, and average daily active minutes compared between treatment and control groups at baseline and the 12-week follow-up assessment. We will conduct multilevel models with baseline-residualized gain scores for outcomes to identify the effect size for the treatment program on each of the three primary outcomes. Each model will include the baseline outcome covariate as well as additional disease covariates including diabetes technology use and length of diagnosis. All participants will be used in analyses, with missing data addressed with full information maximum likelihood estimation. A power sensitivity function was generated wherein our pilot study analyses were used to determine expected effect sizes. Anticipated effect sizes based on our pilot work for between group differences in behavior-change skills and average daily active minutes are Cohen's d of 0.4 to 1.2. With 60 participants, we will have 80% power to detect a Cohen's d of .7, 60% power to detect a Cohen's d of .6, at 95% power to detect a Cohen's d of .8. Thus, we will be powered to detect all but the smallest of potentially meaningful effects found in our previous intervention pilot work.

In aim 2, we test the impact of the Activate program on secondary mechanisms of biobehavioral self-regulation systems and glycemic and cardiovascular disease risk outcomes closely linked with type 1 diabetes health disparities. To assess changes in putative mechanisms and secondary outcomes we will use baseline-residualized gain scores in multilevel models to identify the effect size for the treatment program on each of the secondary outcomes assessed for behavior regulation, distress, c-reactive protein, mean and variability in daily blood glucose, and cardiovascular disease risk score. For all analyses missing data will be addressed with full information maximum likelihood estimation. A power sensitivity function was generated wherein our pilot study analyses were used to determine expected effect sizes. Based on our pilot work we anticipate effect sizes from Cohen's d of .4 to .8 and thus with 60 participants, we will again have 80% power to detect a Cohen's d of .7, 60% power to detect a Cohen's d of .6, at 90% power to detect a Cohen's d of .8. We will be powered to detect all but the smallest of potentially meaningful effects found in our pilot work.

Risks/Benefits: Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.

Risks and Procedures to Reduce Risks

First, there are no adverse effects anticipated for participation in the questionnaires. We use questionnaires widely used in psychological studies in adolescents. In addition, there are no adverse effects anticipated from learning evidence-based behavior change skills. Teaching behavior changes skills is a commonly used evidence-based strategy to increase health behavior change in children and adolescents. Participating in these tasks, surveys, and skills pose no more risk than that experienced in the everyday lives of adolescents, e.g., reading, learning, answering questions, solving puzzles. Should any participants report discomfort with these activities we will both provide access to a list of national resources for mental and diabetes health as well as physical activity supports and the RA participating in the assessment or intervention program can provide in-the-moment support and debriefing supervised by the PI who is a licensed clinical psychologist.

Second, there is also minimal risk associated with involvement in the physical activity incentives program, such as, for example, overexertion when increasing physical activity or changes in glucose levels during and after physical activity. The level of physical activity promoted in this study does not exceed typical activity levels beyond what adolescent already participate in during everyday life (30 minutes physical activity in a day is only half of the CDC and AHA recommendation 60 minutes of daily physical activity for children and adolescents) including physical education classes and is less than would be experienced in many sports. Participation in this program brings no more risk than adolescents already experience in everyday life physical activities (e.g., walking, playing basketball, riding a bike). For adolescents with type 1 diabetes, decreases in blood glucose often occur following physical activity, and as in all daily life activities for persons with diabetes, adolescents will need to manage high and low blood glucose levels through changes in physical activity. To encourage optimal diabetes management during the program, education and support are provided. In the introduction to the Activate Program, the ADA recommendations for managing glucose levels during physical activity are reviewed as well as participants responsibility to communicate with their diabetes provider about any possible changes in diabetes management plans throughout participation, following standard care recommendations for type 1 diabetes. Learning to manage diabetes through physical activity is a key feature of all diabetes education that families participate in with their diabetes providers. Our text-based program also includes reminder to treat low and high blood glucose before exercise. Physical activity programs for youths with type 1 diabetes have been shown to be feasible, acceptable, safe, and health promoting (Knox et al., 2019; Quirk et al., 2018; 2020, Chetty et al., 2019; Marshall et al., 2020).

Third, risks of the project include the potential risk to confidentiality; however, this risk is attenuated through consistent data management. All study data will be confidential and accessible only by IRB-approved study personnel. Results from the online surveys, computerized behavior tasks, and physical assessment will be entered directly into the password-protected study database and/or stored on secure UVM servers. Each participant will be assigned a unique identification code (study ID) to maintain confidentiality. Participants' names, contact information (telephone number and e-mail address), informed consent documents, and payment form and a document that is the master list (key to the code) describing each participant's ID number will be kept in a secure file through RedCap separate from questionnaire and other study data. Participation will entail using participants' e-mail address and/or telephone number to send study surveys and from some the text message communication in the intervention program. This information will not be combined with deidentified data. During the consent process, we will inform all potential participants that, if they decide to participate, we will use their telephone number and e-mail address in order to deliver our text message program and send links to surveys. Participants contact information will remain confidential and will not be accessible by anyone other than those previously described. All research personnel will receive training in confidentiality.

Potential Benefits of the Proposed Research to Subjects– No benefits can be guaranteed, however, participants may directly benefit if assigned to the Activate group as in our pilot work and existing studies behavior change skills and physical activity improved behavior regulation, glycemic outcomes and cardiovascular health. Overall, the risks are minimal

whereas the potential benefits to the participants are substantial. We therefore find the risk-to-benefit ratio to be acceptable.

Importance of the Knowledge to be Gained – The knowledge to be gained is of scientific and practical importance. Participants may also indirectly benefit by contributing to the gathering of data to develop more effective interventions for adolescents with type 1 diabetes. We believe the new scientific information to be gained outweighs the minimal risks involved in the project.

Therapeutic Alternatives: List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well.

☐ **Not Applicable**

If parents/guardians do not wish their adolescent to participate in the study, but do wish to seek help for any diabetes management problems their adolescent may be having, they can contact their adolescent's pediatric endocrinology doctor for assistance.

Data Safety and Monitoring: The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator's plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP.

Data and Safety Monitoring Plan –As noted above, risks associated with this study are minimal and are not believed to exceed those adolescents already encounter in daily life. Specifically, the behavior change skills training and physical activity program is designed to help participants come closer to meeting the widely accepted guideline of engagement in at least one hour of moderate intensity physical activity each day (AHA and CDC[61,62]). This level of involvement is believed necessary to yield optimal health benefits in persons with diabetes (ADA[64]). Consequently, given the minimal risk nature of the protocol, the primary monitor of the data and participant safety will be Drs. Hughes Lansing; this monitoring will occur on an ongoing basis, with the status of participant adolescents discussed at weekly meetings. Any adolescent experiencing difficulty with the physical activity program will be referred via the adolescent's parents to their physician for evaluation. The research team will document and review any adverse events that occur for each participant during the study. At baseline and 12-week follow up appointments, a research assistant will complete an adverse event form with the participant where they will be asked about any adverse events they have experienced over the past 3 months, in order to compare adverse events pre and post study, and between study conditions. Participants randomized to the intervention program will also have access to the adverse events form throughout the study period for additional reporting should they require it. We will also have an independent medical monitor review our summary of adverse event reports. Any adverse event will be reported to the local Institutional Review Board (IRB) in accordance with local guidelines. In addition, Dr. Hughes Lansing will be responsible for assembling the study data and assisting in the preparation of annual data and safety monitoring reports. She will ensure that all monitoring plan personnel obtain copies of these reports in a timely fashion, prior to the deadline for each review. Dr. Hughes Lansing will also oversee all communications with the Office of Research Protections to specifically include initial study approval; ongoing continuation reviews; and any necessary reporting of protocol deviations, protocol modifications, personnel changes, or adverse events.

Define criteria to be used for decision making regarding continuation, modification, or termination of the entire study (not individual participation) (i.e. "stopping rules).

Diabetes behavior change skills training and physical activity promotion with incentives are standard health behavior change strategies with a strong evidence base in adolescents and adults. We have also pilot tested these intervention components to address issues of feasibility and acceptability. Thus, we do not anticipate any early stopping or termination of the entire study. We will engage in continuous review of feedback from participants and if any substantial patterns arise in attrition, feasibility or acceptability, we will pause recruitment to revise intervention components to address those concerns. Following modification to intervention, recruitment would continue and continuous review of feedback from participants will begin again. Should unexpected adverse events arise we will coordinate with our research team and UVM Research Protections Office to identify the appropriate plan of action including: 1) continuation of the trial using the current protocol, 2) continuation of the trial with modifications, 3)

placing the trial on hold until clarifications requested by the UVM Research Protection Office are resolved, or 4) termination of the trial.

What will be the frequency of the review? Please note that the frequency of reviews should be commensurate with the risk of the study. At a minimum, a review of the data should be conducted annually at time of continuing review. **Forward copies of the data and safety monitoring reports to the 1) IRB, 2) CRC (if applicable), and/or 3) UVMCC (if applicable).**

- [ ] Monthly
- [ ] Quarterly
- [ ] Bi-annually
- [x] Annually
- [ ] Other (e.g. by dosing level, no. of subjects enrolled):

Will the sponsor be conducting data monitoring visits for this study?

[ ] Yes [X] No [ ] NA

If yes, how often?

Adverse Event, Unanticipated Problem (UAP), Reportable New Information (RNI): Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in the "Adverse Event and Unanticipated Problems Reporting Policy" will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP.

Should any adverse events, unanticipated problems or reportable new information arise, the PI will contact the IRB according to the Adverse Event and Unanticipated Problems Reporting Policy using the UVM Reporting Form.

Withdrawal Procedures: Define the precise criteria for withdrawing subjects from the study. Include a description of study requirements for when a subject withdraws him or herself from the study (if applicable).

At any time, a participant can choose to withdraw from participation. We do not anticipate withdrawing any adolescent from the study but reserve the right to do so under unforeseen circumstances. These might include situations such as discovery of a medical problem indicating the adolescent should not participate in physical activities If a participant is withdrawn or withdraws from participation their data will not be included in analyses.

Sources of Materials: Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.

All data is being collected solely for research purposes. Participants will provide dried blood spot assays, measurements of abdominal circumference and blood pressure as well as complete computerized self-report questionnaires. This data will be coded at the time of collection.

DRUG INFORMATION

Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures.

Drug (s) [x] **Not applicable**

Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology; vial or product sizes and supplier. If a placebo will be used, identify its contents and source.

Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare.

Storage and stability – for both intact and mixed products.

Administration – Describe acceptable routes and methods of administration and any associated risks of administration.

Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also, adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details.

Is it FDA approved: (include FDA IND Number)

1. in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form.
2. for the route of administration specified? If no, provide justification for route and describe the method to accomplish.
3. for the intended action?

SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT

Subject Selection: Provide rationale for subject selection in terms of the scientific objectives and proposed study design.

This study examines an intervention to reduce health disparities for adolescents with type 1 diabetes and socioeconomic disadvantage. Our goal is to recruit a heterogeneous sample of families with and without SED to achieve a comparison of this intervention's feasibility with adolescents with type 1 diabetes and SED. We will recruit 60 adolescents aged 13-17 years old with type 1 diabetes, through a mixed clinic-based and national advertising recruitment method established with our research team that leverages Facebook, Instagram, and Google Ads resulting in a nationally representative sample (see attached advertisement). We believe these recruitment strategies will allow us to obtain a heterogeneous sample. Inclusion criteria will be the adolescents being at least 18 months post-diagnosis (due to a "honeymoon" period for glycemic outcomes in the first year after diagnosis), parent reported moderate to no physical activity for adolescent, ability to complete measures and intervention program in English, access to broadband or cellular internet, and currently residing in and receiving healthcare in the United States. In order to recruit a heterogeneous sample that aligns with our research goals, we will modify our recruitment criteria after we have enrolled 30 participants in the study. This modification will include the addition of the following inclusion criteria: adolescent is from a marginalized racial or ethnic group. Exclusion criteria will be ward of state, active psychosis, severe medical or psychiatric illness that limit participation (including any contraindications for physical activity per parent report on the physical activity readiness questionnaire). We are specifically recruiting adolescents aged 13-17 with type 1 diabetes and socioeconomic disadvantage due to the specific developmental challenges associated with disease management during this developmental period and the importance of this period for reducing future health disparities.

Vulnerable Populations: Explain the rationale for involvement of subjects (e.g., cognitively impaired, Non-English speaking, prisoners, students). Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.).

x **Not applicable**

Inclusion/Exclusion Criteria: Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research.

Inclusion criteria will be the adolescents aged 13-17 years old with type 1 diabetes, at least 18 months post-diagnosis, parent reported moderate to no physical activity for adolescent, ability to complete measures and intervention program in English as well as access to broadband internet with a computer, tablet, or smartphone, and currently residing in and receiving healthcare in the United States. After 30 participants are enrolled into the study, inclusion criteria will also include that the adolescent is from a marginalized racial or ethnic group. Exclusion criteria will be ward of state, active psychosis, and/or severe medical or psychiatric illness that limit participation for the youth (including any contraindications for physical activity per parent report on the physical activity readiness questionnaire).

Eligibility will be determined during the recruitment process by the research team member using self-report of the parent and adolescent.

Inclusion of Minorities and Women: Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.

We will ensure representative inclusion of persons of color, women (13-17 years old), and people with socioeconomic disadvantage through our national recruitment method that includes recruitment in communities that share these characteristics. In addition, to ensure we are enrolling participants from minority groups, we will modify our eligibility criteria after we enroll 30 participants in the study, to enroll only persons of color.

Inclusion of Children: Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. Provide target accrual for this population. Identify whether children are wards of the state. **If children are excluded** then provide appropriate justification.

We are specifically recruiting 60 adolescents aged 13-17 with type 1 diabetes due to the specific developmental challenges associated with disease management during this developmental period and the importance of this period for reducing future health disparities. We anticipate that 60 adolescents will provide sufficient power for examining effect size changes of the intervention (see analysis section).

Our team is uniquely suited to conduct this work as we have recently developed and tested both neural and self-report measures of learning for adolescents with type 1 diabetes and scalable physical activity interventions for youths. PI Hughes Lansing is a child clinical health psychologist with over 15 years of training in working with adolescents with type 1 diabetes and other chronic diseases including online intervention research. We have not included children that are wards of the state in this study, this is an exclusion criteria. The challenges children that are wards of the state face around diabetes management make engagement in this intervention implausible.

For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.

n/a

If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.

x **Not applicable**

Will the SONA Psychology Pool be utilized? *Include documentation indicating permission to use this recruiting tool* Yes [ ] No [x]

FINANCIAL CONSIDERATIONS

Describe all potential research related expenses to subjects:

There is no expense to participant adolescents or their parents/guardians except for their time required to complete the study and the use of internet to complete the assessment and receive study messages.

Compensation for participation: Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.

☐ **Not applicable**

All Adolescents will receive $25 for the intake assessment and $50 for the follow-up assessment on a study provided cash card or gift card. Adolescents in the control group will be provided an incentive for wearing their Garmin fitness activity tracker, $.50/day up to $42. Adolescents in the intervention group can earn up to $430 for meeting physical activity goals as a part of the incentives program. This amount is common for incentives programs and meets Medicaid guidelines for $500 in annual incentives.

Research Data Management Plan: The Research Data Management and Security Plan form must be completed. The form, along with guidance, can be found in our forms library and must be submitted with your initial application.