Title: Novel mHealth Physical Activity Intervention for Youth With Type 1 Diabetes Mellitus

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PROTOCOL TITLE: Novel mHealth Physical Activity Intervention for Youth with Type 1 Diabetes Mellitus

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
		9.2 Clarification of PHI 9.2;10.1; 21.1 Updated language for consistency to Study Information Letters from Study Information and Letters/Information Letter 16.1 Clarification of consistency regarding benefits of patient participation	

		23.3 Updated enrollment log to show PHI will be temporarily kept and reflected that change in section 9.2 noting an enrollment log will be kept containing PHI and will be destroyed at the end of study 25.0 Virtual visits will not be recorded, so that box was not checked 31.0 Clarified that a CM approved method will be used	
3	March 2023	Updating formatting throughout the document (font, margins) for consistency, survey types (section 11), accelerometer type (section 5.3, 10.1, 15.1, 25.1, 27.1), study objectives (2.0), corrected references for assessments (11, 34). Updated section 6 to accurately describe the Nudge system. Updated section 7 to include a CGM eligibility requirement for data collection requirements	Yes

		Updated Section 10 to clarify the activity calendar would just ask about scheduled physical activity and included information about the sleep diary. Included the sleep diary in section 11. Updated section 31 and 32 with information about collaborators & multi-site setup. Updated section 23.3 to clarify that collaborators will have access to patient telephone numbers and addresses and clarified location of the Nudge server Updated information letter with the location of collaborating sites, surveys, changed "Garmin" to "actigraph" in the study calendar, and made the information more clear. Updated the Treatment Satisfaction survey to correct some grammatical errors (question 4 did not have the correct "Yes, Definitely" response)	

4	May 2023	Updated section 5, 10, and 18 to include actiwatch recording (instead of accelerometer) Updated study population and inclusion exclusion criteria to 13 YOs to streamline study start up. Updated payment plan per new guidelines. Updated section 32 to include KUMC student who will be working on the protocol. Updated information letters to include information on the student worker, update the accelerometer to actiwatch, clarify daily surveys, clarify the payment schedule, and provide next steps after study enrollment Edited survey request emails to include Nudge in the subject line and message Edited Baseline survey to updated Q 9 in the TSRQ and 13 in the TSRQ-D to include a number box for recording the subject response	Yes

		Added “Cell phone number” to Baseline survey to help with contacting participants Corrected answers 17-21 for the POMs in Nudge Day 1-7 Added in messages for EMA surveys for Nudge Days 1-7 Added surveys sent to parents or patients to confirm eligibility and receive information letter Created a letter to link participants to a survey to alert the study team that the study devices were received Created the study device received survey Edited EMA surveys to the correct survey title (EMA day 1 A, etc.), and include time question (AM vs. PM)	
4.1		Updating KU & Kansas University term to University of Kansas in and KUMC to University of Kansas Medical School for clarity in sections 23.3 and 32. These corrections were also made in the information letters.	Yes
4.2		Updated University of Kansas Medical School to University of Kansas	Yes

		Medical Center in section 32. These corrections were also made in the information letters. And removed Susanna Patton email from intro (typo) And corrected reference 13 & 19 (typos)	
4.3		Corrected and confirmed names of Kansas University at Lawrence and KUMC to keep institution responsibilities clear. This was in section 23.3 and 32. Also updated the study calendar in section 5.3 to correct HbA1c to "SOC" and Device uploads to "Daily" timeframes. Calendars in ICFs have also been updated.	Yes
4.4	August 2023	Added in insurance type as piece of information recorded in section 25 (and table in section 25) Added in to study information letter Updated 25.1 demographics list, and incorporated the Diabetes Data Dock	Yes

		at CMKC and using the health API and diabetes data mart, and specifying Diabetes Data Dock for data storage in section 28.1 Also updated 25.1 to specify the Diabetes Data Dock will verify/ extend demographics data listed in the list of data collected in demographics surveys Added payment for exit survey completion section 18.1 Updated recruitment methods to reflect primarily virtual recruitment section 9.2 and 10.1 Updated section 28.1 to clarify the study records will be stored per CM policy, and a data scientist assigned to the study will have access to the study information Also updated the RTDA and Diabetes Data Mart to diabetes Data Dock, as this is the new title of the data processing system. Information letter: Added in insurance type as information	

		collected, the payment for the Exit survey, the study contact information, and updated the language coordinators connect to for participant to connecting to the Garmin Health API app. Added Claire Petty as the lead coordinator	
5	February 2024	See Summary of Changes document	Yes
5.1	March 2024	Section 21 updated for clarity Section 22 language added to reflect process of assent capture	Yes
5.2	March 2024	Section 9.1 updated to reflect use of self-referral Section 21 updated to include applicable study groups	
5.2.1	March 2024	Section 32 Nemours Children's spelling error corrected	
5.3	May 2024	Inclusion/Exclusion criteria updated to include required access to smart device	

Table of Contents

STUDY INFORMATION

1.0 Study Summary

1.1 Synopsis

Study Title	Novel mHealth Physical Activity Intervention for Adolescents and Young Adults with Type 1 Diabetes (T1D)
Study Design	Non-randomized, longitudinal cohort study to pilot an intervention
Primary Objective	To evaluate feasibility and initial efficacy of a novel mHealth intervention to promote physical activity in youth and young adults with T1D
Secondary Objective(s)	To examine if increasing minutes of daily PA in youth and young adults with T1D promotes more optimal HbA1c levels.

Research Intervention(s)/ Investigational Agent(s)	Novel mHealth intervention (i.e., uses daily two-way text messaging) designed to promote physical activity in adolescents and young adults.
IND/IDE #	NA
Study Population	Patients 13.00 to 21.99 with T1D
Sample Size	250
Study Duration for Individual Participants	4.5 months (timeframe between standard of care visits)
Study Specific Abbreviations/F Definitions	T1D= Type 1 diabetes HbA1c= glycated hemoglobin PA= physical activity YA(s) = young adult(s) MVPA= moderate to vigorous physical activity NUDGE= Network Underwritten Dynamic Goals Exchange EMA= ecological momentary assessment

2.0 Objectives

2.1 Purpose, specific aims or objectives: *Describe the purpose, specific aims, or objectives. If more than one objective be sure to list separately.*

The study objectives are to examine feasibility of a novel mHealth intervention to promote physical activity (PA) in youth and young adults (YAs) with type 1 diabetes mellitus (T1D). The study objective is to examine initial efficacy of a novel mHealth intervention to promote PA in youth and YAs with T1D.

2.2 Hypotheses: *State the hypothesis to be tested.*

AIM 1: Test feasibility and initial efficacy of a novel mHealth intervention to promote PA in youth and YAs with T1D.

Hypothesis 1: Our application of a novel mHealth intervention to promote PA in youth and YAs with T1D will show feasibility based on ≥50% of daily text messages exchanged between youth and the intervention bot.

Hypothesis 2: Our application of a novel mHealth intervention to promote PA in youth and YAs with T1D will show initial efficacy based on the threshold of achieving at least a medium effect size for participant's daily PA.

AIM 2: Evaluate if increasing minutes of PA in youth and YAs with T1D promotes more optimal HbA1c levels.

Hypotheses 3: Youth and YAs with T1D who increase their daily PA based on our novel mHealth intervention will also show an improvement in their HbA1c levels.

3.0 Background

3.1 *Describe the relevant prior experience and gaps in current knowledge.*

There are approximately 200,000 children in the US (0-18 years) living with type 1 diabetes (T1D) and nearly 18,000 children diagnosed annually,[1-3] making T1D the third most common chronic illness of childhood.[4] T1D requires a rigorous, complex, and time-consuming daily self-management routine in order to achieve blood glucose levels that approximate the normal range.[5] One component of this self-management routine is daily PA. The American Diabetes Association (ADA) recommends that youth with T1D achieved at least 60 minutes of moderate to vigorous physical activity (MVPA) daily.[5] Moreover, in a recent consensus statement, the authors note a number of unique benefits to youth with T1D who achieve this daily MVPA target, including reduced glycated hemoglobin (HbA1c) levels and improved cardiovascular disease risk profiles, endothelial function, and blood lipid profiles (viz., triglycerides and total cholesterol).[6] Yet, despite these health benefits, most studies suggest that youth with T1D do not meet daily recommendations for MVPA.[7,8]

There are examples of previous PA-focused interventions for youth with T1D, but only a few of these interventions focused on increasing daily PA in youth's daily lives (versus targeting periodic structured PA training sessions).[9] Moreover, there are no examples of PA-focused interventions for adolescents and YAs with T1D that use an mHealth approach, despite the high likelihood that adolescents and YAs might find this treatment approach more feasible and acceptable than a traditional in-person or structured exercise-based intervention[10]. Specifically, in-person exercise-based interventions may have multiple barriers for youth with T1D as these interventions may be time intensive, burdensome, and expensive, with most requiring participants to attend weekly sessions over multiple months. Additionally, face-to-face interventions could be difficult to disseminate if major segments of the population have limited access to healthcare resources necessary to deliver the treatment [11] mHealth interventions include interactive and communication technologies to improve health or health care. Eighty-eight percent of teens own or have access to a cell phone, [12] indicating that mHealth interventions in the form of a mobile phone platform would be widely accessible to adolescents. Further, previous literature suggests that mHealth interventions [13] have a small but significant

effect on changing health outcomes in pediatric populations.[13] However, most mHealth interventions for PA do not utilize behavioral change techniques that are based on theory or are empirically supported. [14] Incorporating both theory and empirically based techniques would likely increase the effectiveness of mHealth physical activity interventions. [15]

3.2 *Describe any relevant preliminary data.*

Cybernetic control theory is a model of self-regulation that postulates individuals monitor their current performance compared to a goal or standard. A negative feedback loop operates to reduce any discrepancy between one's current performance and a set goal. Key behavioral change techniques consistent with this model include goal setting, self-monitoring, feedback, and goal-review. Prior literature has shown interventionist employing control theory behavioral change techniques are effective in changing PA behaviors. [16] Specifically, in a meta-analysis of PA interventions, researchers found that PA interventions that included combinations of self-monitoring with other behavioral change techniques from control theory (i.e., goal setting, feedback) were significantly more effective than interventions that did not include these combinations. [16]

Previous literature in youth also indicates that self-monitoring is a key behavioral change strategy that should be included in mHealth physical activity interventions. [15] For example, in a recent review of mHealth interventions, researchers found self-monitoring was a crucial component in changing exercise behaviors in adolescents. [15] Currently, the majority of mHealth text messaging interventions for PA consist of static or reminder-based text messages. [17] Developing adaptive interventions, which include personalized feedback and intervention content through text messaging, may improve the efficacy of an mHealth PA intervention for adolescents. Specifically, ninety percent of adolescents exchange text messages daily. [12] This suggests that an mHealth PA intervention utilizing text messages may be an effective way to communicate with adolescents.

3.3 *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge.*

Rationale

Here, we propose to pilot test the application of a novel and brief mHealth intervention to promote PA in youth and YAs with T1D. Our intervention, NUDGE (Network Underwritten Dynamic Goals Exchange), [18] utilizes intervention strategies consistent with control theory that have been shown to increase physical activity by encouraging participants to set daily physical activity goals, actively self-monitor progress, receive feedback, and review/revise their future goals.[18, 19, 20] Further, the adaptive features of NUDGE allow participants to set individualized physical activity goals, within a predefined range (i.e., +/- 15 minutes) of their last self-monitored physical activity value and receive immediate feedback. In a previous trial of NUDGE in adolescents without a chronic health condition (n=20 received NUDGE, n=20 controls), we found a medium effect size of NUDGE on adolescents' PA (d=0.63) and a large effect size on

adolescents' minutes of sedentary behavior (d=0.87). Therefore, NUDGE appears to be initially feasible and effective for youth and YAs in general. Prior data suggests a logical next step may be to pilot test NUDGE in a sample of youth and YAs with T1D, a vulnerable patient population with below target levels of daily PA.

Also, see above mentioned literature studies and rationale in 3.1 and 3.2 for additional background, significance of existing literature, and rationale.

4.0 Study Endpoints

4.1 *Describe the primary and secondary study endpoints.*

The primary endpoint is to increase daily PA in pediatric patients with T1D. The secondary endpoint is to improve HbA1c levels in pediatric patients with T1D.

Initial Efficacy Assessment. We will evaluate initial efficacy based on change in minutes of daily MVPA in adolescents from baseline to post-treatment, change in minutes of daily SB in adolescents from baseline to post-treatment, and change in HbA1c levels in adolescents from baseline to post-treatment.

4.2 *Describe the primary and secondary safety endpoints.* **NA**

5.0 Study Design

5.1 Study Design: *Describe and explain the study design.*

We propose to pilot NUDGE in youth with T1D and look at treatment effects after at least 3 months. We anticipate the entire pilot study will last 12 months.

5.2 Schema: *a schema is a representation of your study design in the form of an outline or a model. Including a schema is not a requirement but can be valuable tool in the presentation of your study to the IRB. Consider adding a diagram that provides a quick "snapshot" of the study.*

Study Visit Procedures

5.3 *Table of Events*

	Consent (Day -10 to -5)	Visit 1 (Day 1 to 7)	Day 25	Visit 2 (Day 30 to 37)	Day 85	Visit 3 (Day 90 to 97)	Daily	PRN (SOC)
I/E Criteria	*X*							
E-Consent PAC	*X*							
Baseline Survey	*X*							

Medical Chart Review for demographics	*X*							
Medical Records – HbA1c	*X*							*X*
Medical Records – device uploads	*X*						*X*	
PA Calendar	*X*							
PA Goal Set	*X*						*X*	
Actiwatch Shipment	*X*		*X*		*X*			
Actigraph Shipment	*X*		*X*		*X*			
Participant wears Aciwatch		*X*		*X*		*X*		
Participant wears Actigraph		*X*		*X*		*X*		
Participant to complete EMA REDcap Survey (7 days, 4x/day)		*X*		*X*		*X*		
Treatment Satisfaction Survey and Post Survey						*X*		

All questionnaires are outlined in Section 11.0.

6.0 Study Intervention/Investigational Agent

6.1 Description: *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

NUDGE mHealth intervention. NUDGE is a brief mHealth text messaging intervention designed to promote activity in adolescents by allowing them to set, monitor, and receive feedback on daily PA goals through text message. The only PHI required to be entered is a phone number to receive the text messages. Messages in the Nudge bot are sent via the Twilio server

and stored in the SQL firewall protected server. At baseline, the participant will choose a time of day when he/she would like to receive a text message to set a daily PA goal. Plus, he/she will receive a text message to set an initial goal for daily MVPA that is between 15-60 minutes. The NUDGE bot will store this goal in a study-specific database overnight. Then, at the predetermined time the next morning, the NUDGE bot will send a text message reminding the participant of his/her stored goal. In addition, later in the same day, the NUDGE bot will send a text message to prompt the participant to self-monitor his/her PA and share this number (in minutes per day) via a text message. Once NUDGE receives this response, it will store the response in a study-specific database in order to compare it to the previously obtained goal value (from the day before). The NUDGE bot will then provide feedback to the participant indicating whether or not he/she met the predefined goal, and it will request a new goal. At this point the NUDGE bot will only accept goal values that are between an investigator defined range (e.g., 75-125%) of the last self-monitored PA value, so that future performance is tied to past performance and participants cannot set goals that are too high or too low to be useful. Participants with T1D will engage in this intervention for up to four and a half months.

6.2 Drugs or Biologics: *If this study involves the administration or dispensation of a drug or biologic, complete the table below.* **NA**

6.3 Medical Devices. *If this study* ***involves the evaluation of the safety or effectiveness of a medical device*** *(including mobile medical apps), or the use of medical device with a Humanitarian Use Device designation, include the following information:* **NA**

6.4 Behavioral Intervention: *If this study involves a behavioral intervention, describe the intervention in detail. Be sure to address whether the intervention is experimental or considered to be an accepted standard.*

This behavioral intervention includes the use of a mobile app to modify PA. Participants are allowed to set their own goals within guidelines. These goals will be monitored by the app and provide personalized feedback to promote PA. This study explores cybernetic Control Theory, a conceptual model to attain PA goals in pediatric patients which utilizes self-monitoring, feedback, goal setting, and goal review to modify behavior as noted in Section 3.0 of this protocol under the sub-heading 3.3.

SUBJECT MANAGEMENT

7.0 Inclusion and Exclusion Criteria

7.1 Eligibility Criteria: *Describe the criteria that define who will be included or excluded in the final study sample. If the study design includes multiple groups, be sure to list the criteria for each group.*

<u>Inclusion Criteria:</u>

Participants 13.00-21.99 years old
Participants with a physician confirmed T1D diagnosis
T1D diagnosis was at least 6 months prior to study enrollment
Participants are on an intensive insulin regiment (either with an insulin pump or multiple daily injection)
Participants must be using a continuous glucose monitor (CGM)
Participants and parents/LARs of participants less than 18.00 speak/read English
Participants must have regular access to a smart device capable of Wi-Fi or data usage

Exclusion Criteria:

Participants with evidence of type 2 or monogenic diabetes.
Participants with a comorbid chronic condition (e.g., renal disease).
Participants with presence of severe psychiatric disorders.
Participants with a diagnosis of low vision (vision that cannot be corrected with contact lenses or eyeglasses).
Participants with limited mobility that would prevent participant from engaging in daily physical activity, self-assessed by participant.

7.2 Equitable Selection: *Inclusion/exclusion criteria should be both fair and appropriate to the research question. If your study involves inclusion/exclusion criteria based on demographic characteristics such as sex, race/ethnicity, language, provide rationale for the criteria. For example, if excluding non-English speaking subjects, provide rationale for why it is not possible to include non-English speaking subjects.*

This is a small test of change in preparation for future studies that will include non-English speaking populations.

7.3 Vulnerable Populations: *Check any vulnerable [populations that are being targeted for enrollment into the study]: (Members of the following populations may not be included as subjects in the research unless selected here.)*

☐ Children/Minors (under 7 years of age)

☒ Children/Minors (7-17 years of age)

☐ Neonates (infants less than 30 days old)

☐ Neonates of Uncertain Viability (infants less than 30 days old)

☐ Non-Viable Neonates (infants less than 30 days old)

☐ Wards of the State

☐ Fetuses

☒Pregnant Women

☐ Adults with impaired decision-making capacity

☐ CM Employees

☐ CM Students/Residents/ Fellows

☐ Economically or Educationally Disadvantaged Persons

☐ Prisoners

This study will be inclusive of adolescents from 13.00 to 17.99 years of age, a vulnerable population. This inclusion is important to research because T1D affects this age group and more information about PA and management of T1D is needed. Many of the procedures required to collect data as explained in Section 5.0, Study Design, of this protocol are aspects of routine T1D care for youth and thus the risk for coercion/harm in participation is low. Informed assent of adolescents 13.00 to 17.99 will be obtained per CM policy and parental/LAR permission assent will be obtained for all participants in that age group as explained in Section 9.0, Screening and Recruitment Methods, in this protocol.
If an adolescent subject reaches the age of 18.00 during study participation, he or she will be asked to reconsent as an adult to further participation. If active participation is complete, consent will not be reobtained.
Pregnant women may participate as there is no risk beyond that of PA within healthy guidelines and will be set in collaboration with the participant.

8.0 Local Number of Subjects

8.1 *Indicate the total number of subjects or charts to be enrolled locally as well as the accrual goal. If the study includes multiple groups or cohorts, be sure to describe the number of subjects required for each cohort. If one of the groups includes a chart review, each chart is considered a subject and needs to be reflected in the numbers below.*

Target sample size is one group of 50 participants.

	Group 1	Group 2	Totals
Accrual Goal: The number of evaluable subjects/charts you are targeting for the required	50	NA	

endpoint for the study. This number typically is based on statistical input such as a power analysis.			
Anticipated Enrolled/Consented: **This is the number reported at Continuing Review.** Estimated number of subjects/charts that you anticipate you will need to enroll in order to meet your accrual goal above. This can generally be calculated as accrual goal + number of anticipated screen failures + number of potential withdrawals/drop outs.	70		
Anticipated Pre-Screened (if applicable): Estimated number of subjects/charts you anticipate you will screen prior to obtaining permission/assent/ consent. For example, if your study includes a review of medical records to identify potential participants prior to obtaining permission/assent/ consent, this number would be the estimated number of records you anticipate you will need to review in order to meet your accrual goal.	250		

9.0 Screening and Recruitment Methods

9.1 Screening and Identification of Potential Subjects:

How will subjects be identified? (Check all that apply)

☒ Chart reviews

☐ After obtaining permission/assent/consent

☒ Prior to obtaining permission/assent/consent (Pre-Screening)

*NOTE: If pre-screening, you must address Partial Waiver of HIPAA Authorization below in the "HIPAA & Confidentiality" section.

☒ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☒ List of candidates provided through the Data Report Request Form

☒ By their treating physician who will then provide the study team's contact information to the potential subject/family

☒ By their treating physician who will obtain patient/family permission to share contact information with the study team

☒ Self-refer in response to IRB approved advertisements or websites

☐ Subjects will roll-over from another research study: Study #_____

☒ Registry of individuals interested in research opportunities

☐ Past subject list

☐ Other:

9.2 Recruitment of Potential Subjects:

In clinic, telephone, partial waiver of HIPAA authorization for pre-screening/recruitment only.

Study staff will pre-screen potentially eligible youth and YAs to see if they meet enrollment criteria. Study staff may contact families who appear to meet criteria by reaching out via phone or CM approved conferencing platform and approaching families during a standard of care visit to receive information about this study. If no one answers the phone, only up to 3 voicemails will be left per potential participant and will be tracked on the Pre-screening Log. Recruitment may also involve a report generated by IT that will involve a review of the electronic medical record (EMR) system to generate a list of potentially eligible families. Potential participants may also learn of the study through the intake form, Find A Study page, or the study flyer. The flyer can be posted on the Diabetes Clinic intake form that families complete before appointments or in

clinic spaces. The flyer and Study Information Sheet can be posted on the hospital's Find a Study page.

Study staff will provide youth and their parent/LAR and YA participants information about the study and answer any questions they may have in order to help them determine if they would like to participate as explained in Section 5.0, Study Design. Participants and parents/LARs of youth will have ample time to bring forward any questions or concerns during the period between recruitment contact and the e-consent process. Participants and parents/LARs will be presented with all study information during the e-consent process. At that time informed parental/LAR permission and/or participant assent/consent will be obtained. Study staff will take care to answer all questions and place no pressure on any potential participant or their parent/LAR to enroll.
To minimize risk, we will inform all participants, and parents/LARs of adolescent participants, that they do not have to participate and that a decision not to participate will not affect their care at CM. We will inform all participants and parents/LARs of adolescent participants of the risk of breach of confidentiality as well as these steps we will follow to reduce the risk of a breach of confidentiality and to protect their privacy (e.g., limiting access to data, de-identifying data, securing data in a secure CM network drive). We will inform participants that they can refuse to answer any question during the study. Similarly, we will inform participants that they can refuse to participate in any component of the study protocol and withdraw from the study at any time without penalty or loss of benefits.

We request a HIPAA waiver for the purpose of generating pre-screening lists of qualified candidates for research recruitment as described above. Study staff will record information collected for the purposes of recruitment in the pre-screening log (e.g., eligibility met, contact information, clinic visits where study staff may approach families). Study staff will store personal health information (PHI) on non-participants until completion of enrollment. Study staff will do this to reduce the likelihood of re-approaching families or YAs who have already declined participation in the study. Upon the completion of enrollment, the study team may request a de-identified, aggregate report containing demographic information on individuals who declined enrollment. Study staff may use this information to compare recruited individuals to non-recruited individuals in dissemination work products (e.g., manuscripts, presentations) so that we can report any biases in sampling the eligible populations. Additionally, PHI such as name, age, etc. will be kept on the enrollment log until study completion at which time, that information will be destroyed.

10.0 Procedures

10.1 *Provide a description of research procedures of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.*

We will recruit eligible pediatric patients from the Pediatric Diabetes Clinic at Children's Mercy-Kansas City (CM) as explained in Section 9.0, Screening and Recruitment Methods of this protocol. We will use a tablet and/or computer and REDCap to collect family survey data, collect information from participant's Electronic Health Record (EHR) upon agreement to participate, and instruct participants in how to wear the actigraph and the actiwatch and track, and share data with the research team as explained in Section 5.0, Study Design of this protocol. Contact with participants via phone/email is explained in detail as well in Section 5.0. This study involves no more than minimal risk and procedures to minimize any potential risk to participants is also explained in Sections 5.0, 9.0 under subheading 9.2, and 15.0 of this protocol.

Visit 1:

Informed permission/assent/consent (PAC) from adult participant or child and parent/LAR will be obtained prior to study procedures being performed. All required elements of PAC will be documented in REDCap as this study will not be in the medical record per CM policy.

The study team will conduct a medical chart review to collect demographic information including date of birth, age, gender, height, weight, race, ethnicity, medical history, date of T1D diagnosis, treatment regimen, T1D-related hospitalizations, number of contacts and visits with clinic staff.

HbA1c is a proxy measure of glycemic control over the past 12 weeks. HbA1c will be collected from medical record via POC measures collected during routine diabetes clinic visits.

Glucometer, CGM, and/or pump uploads from SOC visits may be included to assess frequency of blood glucose checks or insulin delivery as a proxy measure of self-management adherence. We may also calculate mean daily blood glucose, percent high BG, percent low BG, and percent in range for glucose levels[21], and insulin BOLUS scores[22] from participants' device uploads.

Baseline Surveys will be sent to participants via REDCap after informed e-consent PAC is completed. This will include Demographics, Treatment Self-Regulation Questionnaire (Exercise), Treatment Self-Regulation Questionnaire (Diet), Perceived competence for Exercise Questionnaire, Social Support for Exercise Questionnaire, (Family), Social Support for Exercise (Friends), Physical Activity Self-Efficacy Questionnaire, and Physical Activity Attitudes Questionnaire, Power of Food Scale, and Pediatric Quality of Life (PedsQL) Parent Report.

We will collect an objective measure of participants' MVPA based on wrist-worn actigraphs and wrist-worn actiwatches. Youth and YAs with T1D who consent to participate will receive a GT3X actigraph and instructions how to share the data from their GT3X actigraph with the study team. Participants will also receive an actiwatch (Garmin Vivosmart 4 or higher as an additional measure of MVPA. We will use age-appropriate guidelines to identify and calculate daily minutes of MVPA.

We will ask participants to complete a PA calendar in order to track their scheduled PA. This activity calendar will be completed in REDCap. Participants will also answer an open-ended question "What would you like to set your initial baseline PA goal as in minutes?" to help to anchor PA goals for the NUDGE intervention.

Participants may complete questionnaires outlined in section 11.0 electronically with the survey links sent via email or text using Twilio. We will set up the distribution of the EMA REDcap Surveys to be completed 4 times per day with family and/or participants for seven days for the initial 7-day assessment with the actigraph and actiwatch. The EMA Survey includes Negative Affect Scale for Children Questionnaire, Latent Mood Questionnaire, Environment Questionnaire, and a sleep diary. The actigraph and actiwatches will be shipped within 10 days to participants with instructions on how to use both as well as how to return the devices at the end of seven days.

Visit 2:

Set up distribution of the EMA REDcap Surveys with family and/or participant 4 times per day for seven days. The actigraphs and actiwatches will be shipped within 10 days to participants with instructions on how to use the devices as well as how to return the devices at the end of seven days.

Visit 3:

Set up distribution of the EMA REDcap Surveys with family and/or participant 4 times per day for seven days. The actigraphs and actiwatches will be shipped within 10 days to participants with instructions on how to use the devices as well as how to return the devices at the end of seven days.

The REDcap Treatment Satisfaction Survey will be distributed to participants which includes the Client Satisfaction Questionnaire and the Exit Interview and Acceptability Questionnaire.

Returning Study Devices. We will use one of two procedures to facilitate the return of any study-specific devices. First, we will send participants/families a prepaid box in which to return all study-related devices to the research team. Second, if necessary, we may make arrangements to pick up devices during a routine T1D clinic visit.

Feasibility Assessment. We will evaluate feasibility based on: the percentage of time participants wore the actigraphs during the study period, the percentage of daily PA surveys adolescents completed, and the percentage of complete interactions with the NUDGE intervention.

Initial Efficacy Assessment. Refer to Section 4.0, Study Endpoints

10.2 *Blood and Other Specimen Collection:* **NA**

11.0 Surveys and Psychometric Testing:

This study will include questionnaires to assess participants' motivation for beginning/continuing PA, belief in competency/efficacy in regard to PA, social support for engaging in PA, personal attitudes toward PA, satisfaction with the intervention and participation in the study, and what participants did or did not enjoy about this study/intervention. Additionally, participants will be asked about their environment, emotional status, and changes in well-being due to intervention engagement. EMA REDcap Survey includes questions from two validated measures: The Positive and Negative Affect Scale for Children[23] and the Latent Mood Questionnaire[24]. The other measures included in the Baseline survey have also been previously validated: Treatment and Self-Regulation Questionnaire[25], Physical Activity Attitudes Questionnaire[26], Perceived Competence for Exercise[27], Social Support for Exercise[28], the Physical Activity Self-Efficacy Questionnaire[29], Power of Food Scale[30], and Pediatric Quality of Life (PedsQL) Parent Report[31].

Included in Baseline Survey:

Demographic Survey

Treatment Self-Regulation Questionnaires (Exercise & Diet). The treatment self-regulation questionnaires assess motivation for eating a healthy diet and engaging in healthy physical activity. This measure has 15-items that assess autonomous and controlled motivation for engaging in the behavior on a 7-point Likert scale (1= Not at all true, 7= Very true)[25].

Perceived competence for Exercise. The Perceived Competence for Exercise questionnaire is a 4-item scale that assesses an individual's perception of their own ability to exercise on a regular basis on a 7-point Likert scale (1= Not at all true, 7= Very true)[27].

Social Support for Exercise (Family). The social support for exercise questionnaire assesses to what degree family members provided support for the adolescent to be physically active. The measure is comprised of 13-items pertaining to support from friends and 13- items pertaining to support from family. Each item is scored on a 5-point scale (1= None, 5= Very often)[28].

Social Support for Exercise (Friends). The social support for exercise questionnaire assesses to what degree friends provided support for the adolescent to be physically active. The measure is comprised of 13-items pertaining to support from friends and 13-items pertaining to support from family. Each item is scored on a 5-point scale (1= None,

5= Very often)[28].

Physical Activity Self-Efficacy Questionnaire. The physical activity self-efficacy questionnaire is an 8-item instrument used to determine the participant's perception of their own ability to be physically active. Each item is scored on a 5-point scale (1= Disagree a lot, 5= Agree a lot)[29].

Physical Activity Attitudes Questionnaire. The Physical Activity Attitudes Questionnaire is a 17-item measure used to assess adolescent's outcome expectancies for physical activity. The instrument has a positive (e.g., being active would give me more energy) and negative (being active would make me tired) outcomes scale. Each item is scored on a 5-point scale (1= Disagree a lot, 5= Agree a lot)[26].

Power of Food Scale. The Power of Food Scale focuses on the psychological appetite for food and the enjoyment of food. It has been confirmed as a useful measure of patient's appetite for food and related issues[30]. The version used is a 30 measure scale, 15 focusing on general attitudes, and 15 focusing on attitudes toward food the day of the survey.

Pediatric Quality of Life (PedsQL) Parent Report. The PedsQL is a 23 item measure validated for 2-18 Y.O.s, focused on health-related quality of life measures. It is applicable to both populations with and without chronic diseases, and utilizes both self-reported information or parent proxy information[31].

EMA REDcap Survey:

Positive and Negative Affect Scale for Children. The Positive and Negative Affect Scale for Children is a short form (10-items) of the well-validated Positive and Negative Affect Scale that has been adapted and validated for use in children and adolescents. Each item is scored on a 5-point scale (1= Not at all, 5= Extremely)[23].

Latent Mood Questionnaire. To assess a variety of mood states the current study makes use of the three highest loading items for six of the subscales from the Profile of Mood States scale. The constructs represented in the current project are: Anger-hostility, Depression-dejection, Fatigue-inertia, Tension-anxiety, Vigor-activity, and Friendliness. Each item is scored on a 5-point scale (1= Not at all, 5= Extremely)[24].

Environment Questions. To obtain information regarding the location of participants when beginning each EMA survey, five questions will be asked pertaining to location, vegetation, traffic, safety, and the weather.

Sleep Diary. To obtain basic questions about the sleep pattern of the previous night and day (length of sleep, any naps, nap lengths), and see if sleep was disturbed due to T1D management.

Treatment Satisfaction Survey:

Client Satisfaction Questionnaire (CSQ-8). The Client Satisfaction Questionnaire is an 8-item measure of client satisfaction with services they receive[32].

Exit Interview and Acceptability Questionnaire. This measure assesses the participants experience of being in the study.

12.0 Follow-up - NA

13.0 Genetic Analysis Information - NA

14.0 Sharing of Results with Subjects - NA

15.0 Risks to Subjects

15.1 *List the research risks. Research risks are any potential physical, psychological, social, legal, privacy, confidentiality risks or economic harms that may come from participating in the study. This does not include the risk of any procedures conducted as part of standard care.*

There is a slight risk of skin irritation from the actigraph and actiwatches. Because the research requires the collection of PHI, there is a risk breach of confidentiality. There is a small chance that disclosing this information may potentially lead to emotional discomfort for some families. There also is a risk to confidentiality when using the internet. Pregnant women may participate as there is no risk beyond that of PA within healthy guidelines. No additional costs are associated with this study, except the potential of a participant to exceed data allowances for their plan with their cell phone carrier.

If the devices cause more than minimal discomfort, participants will be instructed to notify the study team. Minimizing risk of confidentiality is described in section 9.0. Regarding questions that may cause emotional discomfort, participants will be instructed that they may decline to answer any question that they do not feel comfortable answering. Participants will be informed any fees from their cell phone carrier incurred by exceeding their data plan limit will not be covered by the study. PA goals for participants that are pregnant will be set in collaboration with the participant and limited to healthy guidelines.

15.2 *Indicate whether the researchers believe the risks involved in this study are minimal, or if the study poses greater than minimal risk of harm to subjects.*

The overall risks of participation in this project are no more than minimal.

15.3 *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.* **NA**

15.4 *If applicable, indicate which procedures may have risks to an embryo or fetus, should the subject be or become pregnant.* **NA**

15.5 *If applicable, describe risks to others who are not subjects (e.g. pregnant partner of a male subject)* **NA**

16.0 Potential Benefits

16.1 *Describe the potential of any direct benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits as this will be useful to the IRB in making their risk/benefit determination.*

It is possible that some participants could improve their level of personal fitness and HbA1c level based on using the NUDGE intervention. There may not be direct benefit to being in this study, but by being in this study their child may help researchers find better treatments for people with T1D and how PA may help with managing T1D and other illnesses in the future.

16.2 *Describe the potential of any benefits to society or others related to the possible knowledge gained.*

NUDGE could benefit numerous populations in improving PA and subsequent health benefits that result from increased PA.

17.0 Investigator Assessment of Risk/Benefits Ratio:

17.1 *Please provide an assessment of risk and benefits in the table below. Note, the IRB makes the final determination based upon responses in the two preceding sections.*

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
☒	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

18.0 Payment, Reimbursement and Tangible Property provided to subjects

Will subjects receive payment, reimbursement, or tangible property?

☒ Yes ☐ No *(If No, delete the following subsections)*

18.1 Payment to Subjects*: If providing payment to subjects (e.g. cash equivalent for participation, payment for time off work), select the form of payment:*

☒ Greenphire/ClinCard/Rybbon

☐ Gift Card: (Merchant:_____)

☐ Other: _____

Payment Schedule:

Participants will receive up to $648 of compensation for completion of the Study. See the Table below:

Initial Study Visit	Wearing Actiwatch	Wearing Actiwatch 6/7 days	Completing Each EMA Surveys	Completing EMA Survey 6/7 days	Timely Device Return	Completing Treatment Satisfaction Survey	Total Compensation Possible
$50	$5/day (x21)	$100	$2 ($168 possible)	$100	$75 ($25 each)	$50	$648

To receive timely device return compensation, we ask that participants drop-off or schedule a package pick-up within a week after their wear week/visit finishes. Participants will have a simple two question survey to fill out the based on the date provided and receipt of the item within a reasonable/expected period for shipment, participants will qualify to receive compensation. Compensation will not be withheld from participants due to issues or delays caused by the mail carrier.

18.2 Subject Reimbursement: *If providing reimbursement (repayment to research participants and/or their families to cover out-of-pocket expenses they incur), select the form of reimbursement:* **NA**

18.3 Tangible Property: *If providing tangible property or any item of value given to research subjects for their participation (e.g. a toy, a tote bag, a water bottle, an electronic device), describe:* **NA**

19.0 Compensation for Research-Related Injury – NA, Minimal Risk

20.0 Economic Burden to Subjects

20.1 *Describe any costs that subjects may be responsible for because of participation in the research. This may include transportation to appointments, time away from work, parking, additional lab tests, et cetera.*

The only costs participants may have from participating in this study could be from their cell phone carrier. They may charge participants message and data rates depending on their contract with their cell phone carrier. These charges, if any, will not be covered by this research study.

21.0 Permission/Assent/Consent Process

☒ Written informed permission of parent/LAR for pediatric participants
Study group(s) to which this method applies: Parent/LAR of pediatric participants
☒ Written informed consent of adult participants
Study group(s) to which this method applies: Adult participants (18 and above)
☒ Written informed consent of participants turning 18
Study group(s) to which this method applies: Participants who turn 18 while actively participating in study activities
☒ Waiver of consent of participants turning 18
Study group(s) to which this method applies: Participants who turn 18 and active participation has ended

21.1 *Summarize the methods of permission/assent/consent that will be used for each study group. For example, "Full written permission and assent will be obtained for pediatric subjects in the experimental group. Verbal consent will be obtained from parents participating in the survey portion of the study. For the historical controls chart review group, we are applying for a waiver of parental permission and assent."*

Informed consent will be obtained through e-consent via telephone or CM approved conferencing platform. Participants who turn 18 while actively participating in the study will be reconsented.

We request waiver of consent when patients turn 18 whose **active participation** has ended due to continued use of identifiable data. Unnecessary PHI will be destroyed upon completion of the study however, some PHI will need to be kept (date of enrollment, dates of visits, dates surveys completed) We cannot completely deidentify the data if we are unable to reach the subject.

This protocol, and any subsequent modifications, as well as patient-facing material will be reviewed and approved by the Pediatric IRB at The Children's Mercy Hospital & Clinics.

Regulatory Criteria: *To qualify for a waiver or alteration of parental permission or adult consent, **ALL** of the following must apply. Explain how the study meets each of the regulatory criteria below.*

*Waiver of Consent when patients turn 18 whose **active participation has ended:***

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the participants	The research presents no more than minimal risk of harm to subjects and involves no procedures for which written permission is normally required outside of the research context.
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	We request a wavier of consent when participants turn 18 and are no longer active in the study because we will need some PHI even after study procedures have been completed.

If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	We do include PHI as part of our dataset and will need to continue to use even after participation has ended.
The waiver/alteration will not adversely affect the rights and welfare of the participants	The family will be made aware of this at enrollment. We will not keep any PHI that is not necessary for the study.
Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation	Yes

Assent of Pediatric Participants

☒ Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent.

The study team will assess on a case-by-case basis, using best judgement and ensuring there were no notes in the medical record that indicates a participant would be unable to assent. Parents/LAR and participants will be made aware that participant assent is required upon initial contact. Study staff will ask to speak directly to the pediatric participant prior to the e-consent to answer any questions or concerns. The formal assent discussion will be conducted during the e-consent process and documented through REDCap. The length and content of the e-consent materials offer ample time and information for the participant to make any concerns or questions known and is designed to ensure participant comprehension.

22.0 HIPAA and Confidentiality

HIPAA regulations apply to this study if the data used or accessed relates to:

The past, present or future physical or mental health or condition of an individual;
The provision of health care to an individual; OR
The payment for the provision of health care.

22.1 HIPAA Authorization

Select all applicable methods of HIPAA Authorization that apply to this study. For each selection, click on the " " symbol to expand additional information required (if applicable).

☒ Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form)

☒ Partial Waiver of HIPAA Authorization (e.g. waiver for recruitment and pre-screening purposes only)

☒ Other: Waiver of HIPAA Authorization at age 18 (authorization will NOT be obtained) for continued use of identifiable data from patients who turn 18 and active participation has ended.

Regulatory Criteria: *To qualify for an alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to your study. Explain how your study meets each of the regulatory criteria below.*

Criteria	How your study meets the criteria
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: Plan to protect PHI from improper use and disclosure: Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: Assurance that PHI will not be reused or disclosed to any other person or entity:	We will protect PHI from improper use and disclosure as it will only be made available to study staff on an as-needed, IRB approved basis as noted in Section 5.0, Study Design, of this protocol. PHI will be destroyed after all publication has been completed. PHI will not be reused or disclosed to any other person or entity.
The research cannot practicably be conducted without the waiver, i.e. explain why you cannot obtain a signature for HIPAA Authorization.	Partial Waiver of HIPAA Authorization: Study staff will need to record information collected for the purposes of recruitment in the pre-screening log (e.g., eligibility met, clinic visits where study staff may approach families) as noted in Section 9.0, Screening and Recruitment Methods, of this protocol. Waiver of HIPAA Authorization at age 18: Permission/Assent will be obtained. The Waiver is limited to continued use of identifiable data from patients who turn 18 and active participation has ended.
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why you need the PHI to do this study.	Study staff will store PHI on non-participants until completion of enrollment. Study staff will do this to reduce the likelihood of re-approaching families who have already declined participation in the study as noted in Section 9.0, Screening and Recruitment Methods, of this protocol. All data collected is needed to meet the study aims.

22.2 *Indicate how the research team will protect the confidentiality of subjects' data during storage, use, and transmission. (e.g. training, authorization of access, password*

protection, encryption, physical controls, and separation of identifiers and data [master list]). Remember: Sensitive CM data, including research data, must be stored on a file server on the CM network domain – not on a workstation hard drive.

Information pertaining to protection of confidentiality of subject's data during storage, use, and transmission can be found in Sections 5.0 and 23.0 of this protocol.

22.3 *State whether a Certificate of Confidentiality has been issued for this study. Certificates are automatically issued for NIH funded research per NIH policy. For non-federally funded research involving identifiable, sensitive information, investigators may apply for a Certificate if desired. See the NIH website on Certificates of Confidentiality for more details.*

A Certificate of Confidentiality has not been issued for this study.

23.0 Provisions to Protect the Privacy Interests of Subjects

23.1 *Describe the steps that will be taken to protect subjects' privacy during recruitment and while obtaining permission/assent/consent. For example, best practice is to obtain permission/assent/consent in a separate area where a private conversation can be had. If this is not possible, be sure to explain what steps will be taken to provide as much privacy as possible.*

Participation in this research study is voluntary. Study staff will notify adult participants and the parents/LARs of youth of the voluntary status of the research at the onset of the study enrollment and receive informed permission/assent/consent during their e-consent study visit as explained in Section 5.0, Study Design, of this protocol and further explained in Section 9.0, Screening and Recruitment Methods, of this protocol. Any potential participant or parent/LAR who declines to participate will not incur any penalty or loss of benefits to which they are already entitled. No change to the participants' or parent's/LAR's medical care will occur as a result of the participation, or nonparticipation in the study.

Recruitment and consent may take place during a routine clinic visit in a private clinic room, over the phone, or over a CM approved conferencing platform.

23.2 *Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.*

Participants will be told that research is voluntary and that they do not have to answer any questions within the surveys that they do not want to answer.

23.3 *Indicate how the research team is permitted to access any sources of information about the subjects and how the research team will protect the confidentiality of subjects' data.*

Any of the research data collected, with the exception of PHI, may be shared in an aggregated form in presentations and publications. At the termination of the study, study staff will destroy the enrollment log and pre-screening log. During the course of the study, study staff will delete the PHI (with the exception of name and MRN) collected on potential subjects who do not wish to participate. Upon completion of the study, study staff will remove all unnecessary PHI in the data collection files and/or convert to a deidentified number. However, certain PHI will be kept: date of enrollment, dates of visits, and dates surveys were submitted.

NUDGE data is stored securely in two locations- the Twilio.com server and a secure server at the University of Kansas. Twilio uses an encryption protocol to protect the data in messages transferred between Twilio and the NUDGE Web application. NUDGE uses the TSL cryptographic protocol and HTTP authentication. These are the highest security levels available from Twilio at the time of the last software update for the NUDGE web app. Second, data are captured on a SQL Server instance behind a HIPAA compliant firewall in the Computing Center at the University of Kansas.

Study staff at Children's Mercy may access and record name, initials, dates of service, date of birth, medical record number, hospital account number, street address, fax number, telephone number, and email address for research purposes.

The University of Kansas team will have access to the participant's telephone number via the Nudge application. They will also have access to the participant addresses as part of PA tracking device shipment.

Research Team members will only access participant information per the methods approved by the IRB. CM approved lockboxes will be utilized to transport any documents containing PHI from one location to another and this will only be done when necessary. Electronic data will be stored and accessed per secure methods approved by the IRB.

Study staff will share as soon as it becomes available any new information gathered during the course of the study which might impact a family's desire to continue in the study.

24.0 Withdrawal of Subjects

24.1 *Describe the anticipated circumstances, under which subjects will be withdrawn from the research without their consent.*

The only foreseeable circumstances of withdrawal from the research without their consent would be subjects not meeting eligibility criteria.

24.2 *Describe any procedures for orderly termination.*

See Section 23.0, Provisions to Protect the Privacy Interests of Subjects, of this protocol for additional information and below in Section 24.3.

24.3 *Describe procedures that will be followed when subjects withdraw from the research, including data retention plans or partial withdrawal from procedures with continued data collection.*

Participants may withdraw from the study at any time, and this will not affect their medical care. Study staff will not collect any study-related data on participants after their withdrawal from the study. Data collected up to withdrawal will be included in the analyses, with the exception of those who are withdrawn from the study for not meeting eligibility criteria.

Also see Section 23.0, Provisions to Protect the Privacy Interests of Subjects, of this protocol.

DATA MANAGEMENT

25.0 Data Collection: (This section is required for all studies.)

25.1 *Provide a general description of the types or categories of data that will be collected during the study (e.g., lab tests, procedure outcomes, length of stay, questionnaires, surveys). You will provide details on identifiable data and sensitive data below.*

This study will be completely integrated into the Diabetes Data Dock at CMKC. Data will be collected and paired with the other wearable devices, such as pump and continuous glucose monitor readings.

The following data may be collected for this study: HbA1c values collected from EHR; device uploads, date of birth, age, gender, height, weight, race, ethnicity, address, phone number (parent, child, close friend), place of birth, primary language, parent age (mother & father), parent education (mother & father), parent occupation (mother & father), family income, parent marital status, medical history, (such as date of T1D diagnosis, T1D-related hospitalizations, treatment regimen, number of contacts and visits with clinic staff, insurance type, and blood glucose data, etc.) physical activity calendars, data from the actigraph, questionnaires and surveys as noted in Section 5.0, Study Design.

Demographic data: We will use a data collection form in REDCap[33,34] to collect demographic data. We may use the Diabetes Data Dock/ electronic health record to verify or extend participant demographic data listed above (e.g., T1D diagnosis, history of T1D-related

complications, T1D regimen). For remote visits, we will share a web URL linking to the REDCap survey. Participants may complete Surveys on iPad for in person visit or at home via email or text using Twilio as noted in Section 10.0, Procedures.

HbA1c data: We will use routine T1D care POC HbA1c levels to at baseline and at post-treatment (~3 months post baseline).

CGM or SMBG data: Families will use their personal, prescribed CGM or standard blood glucose monitor (SMBG) throughout the study. Families will share CGM data with the study team using their personal, CM connected account. To facilitate data sharing, we will ask participants and parent/LAR of youth to please share a .CSV file version of these data. Study staff will save participant's CGM or SMBG in a secured study database using MS Excel or equivalent software. Data will be download automatically to the Diabetes Data Dock using API. This study database will reside in a secured CM approved location.
Garmin data and activity monitor: data will be downloaded and stored on the Diabetes Data Dock using API connection. Primary physical data will be gathered from the Garmin Connect platform. The anonymous participant Garmin data from the Garmin Connect platform will be loaded to a secure database through the Garmin Health API connection developed by Children's Mercy Research Informatics. The Garmin tracker will not collect personal information. Physical activity data will be pulled from the actigraph via the Actilife software and uploaded into the secure database. Also, the patient study record will be linked to the Garmin tracker and the actigraph. The interventionist team will be able to pull the data to Microsoft Azure database to evaluate. Coded clinical data will also be collected from EMR.
Insulin delivery data: Participants will use their personal, prescribed insulin delivery device throughout the study. Participants and parents/LARs of adolescents will share participants' insulin device data with the study team using their personal, CM connected account. To facilitate data sharing, we will ask families to please share a .CSV file version of these data. Study staff will save participant's insulin device data in a secured study database using MS Excel or equivalent software. This study database will reside in a secured CM approved location.

Questionnaire data: We will use REDCap to electronically collect any survey data, including participants' daily activity schedules. We will use a single REDCap database for all study participants. This REDCap data base will reside on a CM secured server.

Name/Initials	☐ Accessed only	☒ Recorded
All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)	☐ Accessed only	☒ Recorded

Medical record number	☐ Accessed only	☒ Recorded
Account number	☐ Accessed only	☐Recorded
Health plan identification number	☐ Accessed only	☐ Recorded
Social Security Number	☐ Accessed only	☒ Recorded
Device identifiers and serial number	☐ Accessed only	☐ Recorded
Certificate/License number	☐ Accessed only	☐ Recorded
Telephone number	☐ Accessed only	☒ Recorded
Fax number	☐ Accessed only	☒ Recorded
Email addresses	☐ Accessed only	☒ Recorded
Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☒ Recorded
Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
Biometric identifiers, including finger and voice print	☐ Accessed only	☐ Recorded
Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded
Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. student or employee ID number)	☐ Accessed only	☐ Recorded
Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded
Other: Insurance type (public vs. private)	☐ Accessed only	☒ Recorded

26.0 Adverse Events and Unanticipated Problems

26.1 Monitoring: *Describe your process for monitoring subjects and data to identify adverse events and other unanticipated problems.*

The only anticipated Adverse Event is potential Breach of Confidentiality. Please see Sections 9.0 (Screening and Recruitment Methods), 23.0 (Provisions to Protect the Privacy Interests of Subjects), 25.0 (Data Management), and 28.0 (Data and Specimen Management), of this protocol for procedures to prevent and/or reduce this risk.

26.2 Reporting: *Confirm that you will be following Policy 5.11 Reportable Events of the CM Research Program Policies in regards to reporting adverse events and other unanticipated problems to the CM IRB. If you will be deviating from or expanding upon this policy, explain why the approved policy would not suffice for this study and the rationale for deviating/expanding.*

Policy 5.11 Reportable Events will be followed.

27.0 Statistical Analysis

27.1 *Describe the data analysis plan, including any statistical procedures or power analysis.*

This is a pilot data collection in order to perform power calculations for a larger study.

AIM 1 and Hypotheses 1 and 2: Refer to Section 3.0, Objectives for explanation.

Data Analysis: We will use descriptive statistics to examine feasibility based on the percent of daily text messages exchanged between youth and the NUDGE bot. This will serve as our primary feasibility assessment. However, we will also consider feasibility based on other parameters including percent of days that youth wear the actigraph and the percent of daily PA schedules that participants complete. We will use multilevel analyses to determine whether the NUDGE intervention increased participants MVPA levels. In particular, we will examine the effect size of NUDGE and interpret at least a medium effect size as our threshold of initial treatment efficacy.

AIM 2 and Hypothesis 3: Refer to Section 3.0. Objectives for explanation.

Data Analyses: We will use multilevel analyses to determine whether the NUDGE intervention improved participants HbA1c levels. As explained above, we will focus on measuring the effect size for change in participant HbA1c for this hypothesis as well.

27.2 *Describe how the sample size for the study was determined (e.g. formal sample size calculation, convenience sampling). To minimize the risks associated with a possible breach of confidentiality, appropriate sample size calculations limit the amount of patient data being recorded to just the amount necessary to answer the research question.*

This is a pilot data collection in order to perform power calculations for a larger study.

28.0 Data and Specimen Management

Specimen Management – NA

28.1 Data Management*: Describe how data will be handled.*

Please see Sections 9.0 (Screening and Recruitment Methods), 23.0 (Provisions to Protect the Privacy Interests of Subjects), 25.0 (Data Management), and 28.0 (Data and Specimen Management), of this protocol for additional information on what information will be included with data, who will have access to that data, and what procedures are in place to mitigate risks.

Data Management:

We will collect and store all study information electronically on a secure division drive on the CM network domain or on Microsoft OneDrive or equivalent. A research data will be processed and stored in the secure Diabetes D- Data Dock and will be processed in the CMRI Data Center. Collection and storage of this data is explained in further detail in Section 10.0, Procedures, of this protocol.

Information will be transferred using a secure file sharing service, such as Azure or OneDrive, which is institutionally approved. The NUDGE bot will also store information on a HIPAA protected server. The NUDGE bot will initially collect phone numbers, but these will be deleted at the end of the study. The information collected by the NUDGE bot, the physical activity and goals set and exercise times reported, will be transferred to CM for permanent storage on a secure CM drive/domain as previously noted.

A Certificate of Confidentiality has not been issued for this study.

Approved study staff (including an assigned data scientist for processing CMRI Data Center data) will have access to research records as explained in Section 9.0, Screening and Recruitment Methods, of this protocol. Lab & study staff will have access to samples as explained in Section 5.0, Study Design, of this protocol. The PI is ultimately responsible for receipt or transmission of the data or specimens.

Data will be stored per the Record Retention and Management Policy and the Record Retention Schedule.

28.2 Specimen Management NA

28.3 Biospecimen Information NA

Will this study involve handling, transporting, or shipping any potentially hazardous biological material at/from a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

Will this study involve processing any potentially hazardous biological material at a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

29.0 Storage/Banking of Data and Specimens for Future Research - NA

30.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects.

Because this intervention presents no greater than minimal risk, we do not propose to assemble a Data Safety and Monitoring Board. PI and study staff will assume responsibility for oversight and safety of participating child/parent or child/LAR dyads. Any known breach of confidentiality will be reported to the IRB.

30.1 *In addition to the Principal Investigator, which individual or group will be responsible for monitoring the data and safety for this study?* **NA**

30.2 ***Data Safety Monitoring Plan:*** *If a DSMB charter or other external monitoring plan is available, upload under "Other Attachments" on the "Local Documents" page in your myIRB submission. If such a charter/plan is not available, describe:* **NA**

STUDY MANAGEMENT

31.0 Setting & Locations

Describe the sites or locations where the research will be conducted.

Identify where research procedures will be performed including any non-CM affiliated locations. For any non-CM affiliated locations, upload a letter of support in myIRB which states that the site is aware that research will be conducted on their premises:

The study visits will take place either remotely via a CM-approved telehealth platform or at the CM Endocrinology clinic during a routine care visit (if preferred by the participant/ family). Non- CM affiliated locations will not be used for research procedures.

Describe the composition and involvement of any community advisory board: NA

For research conducted outside of CM and its affiliates describe:

Regulations or customs affecting the research: NA

The local scientific and ethical review structure: NA

Describe the availability of medical or psychological resources that participants might need as a result of taking part in the study. NA

32.0 Multi-Site Research

Choose ALL relationship types that apply:

☐ ***Multi-Site Research:*** *Multiple sites will be engaged in this human research project. Sites will use the* ***same*** *protocol to conduct the* ***same*** *human research activities (except for minor variations due to local context considerations).*

☒ ***Collaborative Research:*** *Multiple sites will be engaged in this human research project. Sites will* ***not*** *be performing the* ***same*** *research activities. The Site submission will specify the specific research activities each site will perform.*

REQUIRED*: Enter summary of site-specific activities that differ from the overall protocol: Click or tap here to enter text.*

Children's Mercy: Subject screening, recruitment, consent, data collection, surveys, data analysis.

University of Kansas: App management, data analysis

Nemours Children's: Data analysis (deidentified)

University of Kansas Medical Center: No site-specific activities will occur at this site (Student from KUMC will be performing activities Remotely and at Children's Mercy)

☒ ***Student(s)*****:** Student(s) will help with this project and will be engaging their home institution. We are engaging with a student from University of Kansas Medical Center who will be involved in analyzing patient data and patient interaction (survey follow up) at Children's Mercy.

☐ **Visiting *Resident(s)* / Visiting *Fellow(s)*:** Visiting Resident(s) / Visiting Fellow(s) will help with this project and will be engaging their home institution.

Is Children's Mercy (CM) acting as the single IRB of Record (sIRB)?

☐ ***No, each site is getting their own IRB approval.***

☒ **Yes, some or all sites will rely on the CM as the sIRB**.

- **Reliance is required** for non-Exempt **NIH** or other **Federally Funded** research where: NA
  - The institution's employees or agents intervene or interact with human subjects for research purposes.
  - The institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or
  - The institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

If CM is sIRB for another site, complete the chart for that site(s) (*Add a new row for each site relying on the CM IRB, delete chart if not acting as sIRB):*

Site Name	Enrollment Goal for Site(s) *Choose One*	Relying on CM IRB?
University of Kansas	☐ **Site Enrollment Goal:** *Insert #* ☒ **Site will not enroll**	☒ External Site will rely on the CM IRB as the IRB of Record using a reliance agreement. () ☐ **Not Applicable**. Site will **not** interact or intervene with human participants or their identifiable data / identifiable biospecimens. Site is also not a primary NIH or federal grant recipient.
University of Kansas Medical Center	☐ **Site Enrollment Goal:** *Insert #* ☒ **Site will not enroll**	☐ External Site will rely on the CM IRB as the IRB of Record using a reliance agreement. () ☒ **Not Applicable**. Site will **not** interact or intervene with human participants or their identifiable data / identifiable biospecimens. Site is also not a primary NIH or federal grant recipient.

33.0 International Research - NA

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