CASE WESTERN RESERVE UNIVERSITY
Frances Payne Bolton School of Nursing

Stephanie Griggs, PhD, RN, FAAN
Associate Professor
Agnes Stahlin Baun Scholar

Nursing Research Building
2120 Cornell Road
Office NO304F
Health Education Campus
10900 Euclid Avenue
Cleveland, Ohio 44106-0000
Office 459T

phone 216.368.5518
fax 216.368.3542
stephanie.griggs@case.edu

Date: May 14, 2021

Title of Study: Self-Management in Young Adults with Type 1 Diabetes

ClinicalTrials.gov ID: NCT04975230

Please find the most recently approved study protocol.

Sincerely,

Stephanie Griggs, PhD, RN

[USE THIS SOCIAL, BEHAVIORAL, AND EDUCATIONAL PROTOCOL TEMPLATE IF YOUR PROJECT INCLUDES SURVEY, INTERVIEWS, FOCUS GROUPS OR EDUCATIONAL RESEARCH ACTIVITIES WITH NO BIOMEDICAL/CLINICAL COMPONENTS]

INSTRUCTIONS:

- *Use this template to prepare a document with the information from the following sections.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, please mark as N/A. You may delete contents of sections, but will not be able to delete the headings of the sections.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Consider using a different color font for your answers.*

PROTOCOL TITLE:
Include the full protocol title.

Diabetes Self-Management in Young Adults with Type 1 Diabetes During COVID-19

PRINCIPAL INVESTIGATOR:
Name: Stephanie Griggs, PhD, RN
Primary Department: Frances Payne Bolton School of Nursing
Telephone Number: 216-368-5518
Email Address: stephanie.griggs@case.edu

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):
Click here to enter text.

VERSION NUMBER:
Include the version number of this protocol if assigned by an outside entity.
Click here to enter text.

DATE:
5/14/2021

Indicate the origin of this protocol (who conceived of and leads the development of the protocol regardless of funding):

☒ Investigator initiated *(Investigator(s) developed protocol, regardless of funding)*
☐ Industry *(Pharmaceutical, Device, etc.) (Industry developed protocol)*
☐ Federal *(NIH, DOD, etc.)*
☐ Cooperative Group *(SWOG, GOG, etc.)*
☐ Other - Please specify: Click here to enter text.

1.0 Funding

Please list the funder of this project. If there is not a funder, please note that your department pays for your time and resources and should be listed here. National Institute for Nursing Research (NINR), K99NR018886

Has this study been disapproved by or withdrawn from any other IRB?

☐ Yes ☒ No

If so, please explain: Click here to enter text.

*Does this study involve cancer research or cancer-related issues?

☐ Yes ☒ No

If yes, indicate the PRMC number: Click here to enter text.

2.0 Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested. The purpose of this study is to characterize sleep health (quantity, quality, timing, variability), diabetes-self-management, symptoms (general diabetes and emotional), and glycemia (glycemic control and glucose variability) over 7 days in young adults age 18-25 years with type 1 diabetes (T1D) during the COVID-19 pandemic. Aim 1. Determine the prevalence of clinically significant emotional distress, diabetes distress, high-risk sleep apnea, and clinically significant insomnia in 200 young adults with T1D and compare to the prevalence of the general T1D population pre-pandemic. Aim 2. Examine the associations between sleep health, diabetes self-management, symptoms, and glycemia in 200 young adults with T1D. Aim 3. Determine the additional contribution of sleep (quantity, quality, timing, or variability) to the variance in symptoms, diabetes self-management, and glycemia in 200 young adults with T1D. Aim 4. Elicit feedback on a behavioral sleep self-management intervention from 10 young adults with T1D who are at low risk for sleep apnea and do not meet the threshold for clinically significant insomnia.

3.0 Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how it will add to existing knowledge. Include any relevant preliminary data. Type 1 Diabetes (T1D) affects 1.6 million Americans, and only 14% of emerging adults age 18-25 years achieve targets for glycemic control (glycosylated hemoglobin A1C <7.0%) based on national data. Lower A1C levels are associated with reduced risk for both micro- and macrovascular complications, better neurocognitive function, and better diabetes quality of life. Emerging adults with T1D experience frequent sleep interruptions at night, demonstrate less time in slow wave sleep, have a more pronounced sleep extension on weekends, and report sleep that is of poorer quality and less restorative compared to matched controls. Short sleep (duration < 7 hours) and circadian misalignment (inappropriately timed sleep and wake) are associated with poorer glycemic control in emerging adults with T1D. Both short sleep and circadian misalignment may affect diabetes self-management negatively and result in difficulties in performing activities necessary to optimize glycemic control (e.g., checking glucose, responding to results, calculating and administering insulin doses). Therefore, improving sleep

duration and timing may be potential therapeutic targets to improve glucoregulation and clinical outcomes (diabetes self-management, diabetes quality of life, neurocognitive function) in this high-risk population. Sleep plays a critical role in physical, mental, social, and emotional health as well as in the effective functioning of the immune system. Short sleep duration is associated with a higher BMI, an impaired body weight regulation and impaired glucose metabolism. COVID-19 has posed barriers for achieving or maintaining healthy sleep. These barriers may include a disruption in daily life, increased anxiety and worry, worsened depression and isolation, a greater family and work stress, and increased screen time. **Preliminary data:** Forty-six young adults with T1D (67.4% female, mean age 22.3 ± 3.2 years, mean BMI 27.0 ± 4.4 kg/m^2, mean A1C 7.2 ± 1.1%) were recruited from the Yale New-Haven Health System. All study participants (N = 46, 100%) had actigraphy data ranging from 6-14 days/nights (Mean 9.0±2.8 days/nights) and a majority (n = 43, 93.5 %) had continuous glucose monitor data ranging from 6-14 days/nights (Mean 9.5 ± 3.5 days/nights). Shorter total sleep time and greater sleep variability were associated with greater daytime sleepiness (r = -0.47, p = .001 and r = 0.40, p = .005 respectively). Greater sleep variability was associated with neurocognitive function (longer median reaction time *rho* = 0.31, p = .03 and more lapses *rho* = 0.36, p = .01 on the PVT) and greater glucose variability (mean of daily differences *rho* = 0.33, p =.04). Shorter total sleep time was associated with greater diabetes distress symptoms (ß=-0.32, p=.032). Greater sleep variability was associated with greater symptoms of neurological pain (ß=0.32, p=.019) and hypoglycemia (ß=0.32, p=.016). Longer sleep onset latency was associated with greater psychological fatigue symptoms (ß=0.31, p=.024), greater psychological cognitive symptoms (ß=0.37, p=.012), greater hyperglycemia symptoms (ß=0.33, p=.024), and a greater total symptom burden (ß=0.30, p=.042). Poorer sleep efficiency was associated with greater diabetes distress symptoms (ß=-0.35, p=.018) and greater hypoglycemia symptoms (ß=-0.30, p=.027). The associations between the sleep-wake characteristics and general emotional distress symptoms were not significant. Sex and BMI differences were noted for diabetes symptoms. Specifically, females reported greater hypoglycemia and fatigue symptoms and those with a higher BMI reported greater fatigue, neurological pain, and cardiology symptoms. Associations of these sleep-wake characteristics and symptoms remained statistically significant even after adjustment for sex and BMI.

Please add relevant references at the end of the protocol, not at the end of this section.

4.0 Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility.

Participants will self-identify inclusion into the study based on the following parameters listed below

Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	Age range: from 18 to 25 years
2.	Have been diagnosed with T1D for at least 6 months
3.	Have no other major health problems (e.g., chronic medical condition or major psychiatric illness)

4.	Are not currently participating in any intervention studies
5.	Read/speak English

	Exclusion
1.	Previous obstructive sleep apnea (OSA) diagnosis
2.	Current pregnancy
3.	Night shift workers
4.	High risk score on the Berlin Questionnaire (aim 4 only)
5.	Clinically significant insomnia – scores ≥ 15 on the Insomnia Severity Index (aim 4 only)

5.0 Number of Research Participants

Directions: Indicate the target number of research participants to be accrued locally, and, if this is a multi-site study, indicate the total number of research participants to be accrued across all sites.

Example language that can be used: We will enroll 25 subjects at CWRU and plan to enroll 150 subjects study wide. We will enroll 200-300 participants for aims 1-3 and will invite 10-15 participants from aims 1-3 to complete aim 4

6.0 Special/Vulnerable Populations

1. *Indicate specifically if you will include each of the following special populations by checking the appropriate box:*
   - ☐ **Adults unable to consent**
   - ☐ **Minors (infants, children, teenagers)**
     - ☐ Wards of the state/Foster Children
   - ☐ **Pregnant Women**
   - ☐ **Neonates**
   - ☐ **Neonates of Uncertain Viability**
   - ☒ **Employees of CWRU or UHHS**
   - ☐ **Prisoners**
   - ☐ **Illiterate Individuals**
   - ☐ **Non-English Speaking**
   - ☒ **University Students**
   - ☐ **None**

2. If the research involves individuals that are included in a special/vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated. We will be recruiting from social media and the college diabetes network (Case is one of 5 chapters in Ohio). We will not be directly recruiting students or employees of Case Western Reserve University but if they happen to be interested in participating in the study and meet the eligibility criteria for inclusion then they will be included. We mentioned in the consent form that their decision to participate in the study will not influence their employment or

student standing

3. If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable rationale. Pregnancy is a confounder for both sleep and glycemic control which are the major variables under study, some of the validated instruments are only available in English and because a majority of the study will be conducted online it is not possible to translate for individuals who speak other languages

7.0 International information

☒ This is **not** an international study – *please leave rest of this section blank.*

☐ We will be conducting this research at the following international sites:
Click here to enter text.

☐ We are recruiting participants outside of the US from the following locations:
Click here to enter text.

☐ We are sending data outside of the US to the following locations:
Click here to enter text.

☐ We are receiving data from outside of the US from the following locations:
Click here to enter text.

8.0 Recruitment Methods

Note: Attach all applicable recruitment materials to the last section of the Smart form under "Recruitment Materials."

1. Which of the following methods will be used to recruit research participants? – *Select all that apply*
   - ☒ Email
   - ☐ Phone call
   - ☒ Letter
   - ☒ Advertisement (e.g., poster, flyer, etc.)
   - ☒ Social media
   - ☐ Other. *Please specify:* Click here to enter text.

2. Describe when, where, and how potential research participants will be recruited.
A description and link for the study will be posted on the College Diabetes Network site, T1D exchange site, and through social media sites (Facebook, Twitter, Instagram, TuDiabetes). We will also reach out to contacts who have been identified as potential role models to share the pre-approved post on their social media sites. Recruitment will begin once IRB approval has been obtained. Role models will be offered an honorarium of $10 for their assistance. Messages will direct potential participants to a link in REDCap where they can confidentially fill out a form expressing an interest in the study. We will not advertise on Facebook or other sites as described above without IRB approval of the messages or ad(s). The purpose of the honorarium for role models is that the role model

may not participate in the study per se so would not be eligible for a gift card but may have a following on social media to post the link on. The role model would not receive a finder's fee or identify potential participants. We wanted to offer a one-time honorarium for the role model's time to post the study information. The honorarium is compensation for the role models taking time to share our post and tag the study team. This compensation will not be influential to others, as it is not offered to just any person and is not a part of the advertisement. There should not be any undue influence as we are providing an incentive for participation in our study that is in line with other studies of similar designs. The study is longitudinal over 1 week and it seems that breaking down the incentives with a step wise approach as the PI has used in a previous study may be more successful in recruiting a representative sample.

3. Describe the source (e.g., from what department, EMR, etc.) of the research participants. The two primary sources of recruitment are the aforementioned list community outreach through IRB-approved targeted ads on Facebook.

4. Describe the methods that will be used to **identify** potential research participants.
   By social media and for aim 4 those who meet inclusion criteria and agree to be contacted will be invited to participate in a focused interview.

5. Describe the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to?
   The Principal Investigator, Stephanie Griggs and Co-Investigator, Ronald Hickman have proven track records for meeting benchmarks in previous studies.

9.0 Setting

Directions: Describe the sites and locations where your research team will conduct the research.

For the interview component (aim 4) this will be conducted via zoom to be in compliance with the university

10.0 Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe where the consent process will take place: Participants will sign consent electronically in REDCap

2. The time that will be devoted to the consent discussion: N/A, a consent form will be available for participants to read and agree to prior to completing the survey. If participants will participate in the focused interview a separate consent will be obtained to ensure participants are aware that the content will be recorded.

3. Any waiting period available between informing the prospective subject and obtaining the consent: After consent is signed the survey will be available for participation.

4. Steps that will be taken to ensure the research participants' understanding: Participants will be provided with a written consent ahead of time, will be given time to read through the consent, will be provided with a brief summary of the contents of what is in the consent, and will be allowed time to ask questions about the consent document. They will also be provided with a copy of the consent form in case questions arise following the survey or focused interview.

5. Any process to ensure ongoing consent: Participants will be informed that they can withdraw from the study at any time and that they are allowed to skip any question they feel uncomfortable answering.

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects: If the participant is a student in the same department as the PI and wants to participate in the study, someone else on the study team will conduct the interview. They will be informed that participating/not participating will have no bearing on the student's standing in the nursing program. If the participant is a patient in one of the mentor or member of the study team's clinics, someone else on the study team will collect data or conduct the data and the identity will be protected. They will be informed that participating/not participating will have no bearing on the patient's ability to receive care in the clinic.

For Adult Participants

Indicate if you will be asking for a waiver or alteration of consent process or documentation (consent will not be obtained, or written consent will not be documented)

☐ Yes ☒ No

If yes, explain how the research involves no more than minimal risk. Click here to enter text.

Indicate which part of the consent process you are requesting be waived or altered and the rationale for requesting the waiver or alteration:

☐ I will obtain consent, but not participant's signature.

1. Give the rationale for the request of a waiver of signed consent. Click here to enter text.

2. Please describe how you will be documenting that a participant has consented. Click here to enter text.

3. Indicate if the subjects will be provided with written information about the study. Click here to enter text.

☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception).

☐ I will not obtain any consent, and I am requesting a full waiver of consent.

If you are requesting an alteration of consent, or a waiver of consent, please answer the following:

1. Give the rationale for the request of a waiver or alteration of the consent process. Click here to enter text.

2. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants. Click here to enter text.

3. Explain why the research could not practicably be carried out without the waiver or alteration of consent. Click here to enter text.

4. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

**Be sure to upload a consent script or information sheet with your study protocol*

Additional Considerations for Consent Process with Adults

Non English Speakers *(Please select one)*

☒ I am **not** enrolling non-English speaking individuals in this research study. The following is justification for why non-English speaking individuals cannot be enrolled: The instruments have not been translated/validated in languages other than English.

☐ I will be targeting non-English speaking adults

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

☐ I am **not** targeting non-English speaking individuals. If a non-English speaking individual is eligible for the study, we will use the following procedures to enroll:

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

Adults Unable to Consent

☒ I am **not** enrolling adults unable to consent in this research study – *please leave the rest of this section blank.*

☐ There is an anticipated direct benefit to the subject. Explain: Click here to enter text.

☐ There is NOT an anticipated direct benefit to the subject. Explain: Click here to enter text.

1. Describe the process to determine whether an individual is capable of consent. Click here to enter text.

2. List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child). Click here to enter text.

3. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research. Click here to enter text.
   ☐ N/A

4. Describe the process for assent of the research participants. Indicate:
   - Which subjects that are unable to consent will be required to give assent? If not all, explain why. Click here to enter text.

   - Describe whether assent of the research participants will be documented and the process to document assent. Click here to enter text.

   ☐ The subject will be informed about the research to the extent compatible with the subject's understanding.
   ☐ Subjects will be closely monitored.
   ☐ The subject will be withdrawn if they appear unduly distressed.

Research Participants Who Are Not Yet Adults (infants, children, teenagers)

☒ I am not enrolling participants who are not yet adults in this research study. – *please leave the rest of this section blank*

1. Will parental permission be obtained from:
   ☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child

☐ Requesting a waiver of parental permission

If you are getting parental/guardian permission:

a. Indicate how you will be documenting the permission:
   ☐ Signed consent form
   ☐ Requesting a waiver of documentation of parental permission

b. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research. Click here to enter text.

If a waiver of parental permission is being requested:

a. Describe how the study is designed for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects, if applicable. Click here to enter text.

b. Describe how the research could not practicably be carried out without the waiver of parental permission. Click here to enter text.

c. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

2. Will assent be obtained from:
   ☐ all of the children
   ☐ some of the children
   ☐ none of the children

   If assent will be obtained from some children, indicate which children will be required to assent. Click here to enter text.

   When assent of children is obtained, describe how it will be documented. Click here to enter text.

3. For children who are pregnant, describe how assent and permission are obtained. Click here to enter text.
   ☐ N/A

11.0 Sharing of Results with Research Participants

Results will be shared with research participants:

☒ Yes ☐ No

If yes, describe how the results will be shared. Member checking will be done throughout the interview process and participants will be invited back to see the revised intervention based on feedback to ensure the final product does not need further refinement (aim 4). Results will be de-identified and shared as an aggregate.

Results will be shared with others:

☒ Yes ☐ No

If yes, describe with whom and how the results will be shared. Results will be disseminated to scientific journals and presentations. Data will be de-identified and shared in an aggregate format.

12.0 Study Design/Procedures

Directions:

1) Describe the overall study design (e.g.: single visit, single-blind, double-blind, non-randomized, randomized, blood draw, investigational drug, device etc.).
2) Provide a description of all study-related research procedures being performed, including the length of time involved.
3) Include procedures being performed to monitor research participants for safety or minimize risks.
4) Describe the source records including medical or educational records, which will be used to collect data about subjects.
5) Include a description of any device being used to collect data (e.g., eye tracker, step counter). If the device itself is being studied, include additional information in Section 29.

1) This is a multi-method descriptive study using both quantitative and qualitative methods to describe the phenomenon of interest. For Aims 1-3 an online survey will be administered at baseline with twice daily surveys over a one-week period. All surveys will be administered in REDCap. The final questions in the online survey will be if participants are willing to participate in a focused interview via zoom to see the components of a sleep self-management intervention. The presentation and interview (zoom) will be audio recorded and transcribed verbatim. The interview will be conducted with each participant individually. Only those at low risk for sleep apnea and who do not meet the threshold for clinically significant insomnia will be invited to participate in aim 4. For aim 4 we will engage 10-15 emerging adults with T1D on zoom to provide input on content, format, delivery, as well as barriers/facilitators of the proposed intervention. We will partner with the participants and will use a community-engaged approach to increase the likelihood that the intervention will be relevant and acceptable to them. We are presenting a potential intervention and will not be delivering an actual intervention to get feedback on the initial one-hour session. We will collect quantitative and qualitative data and then use the findings to develop the intervention protocol. We will ask participants to provide input on how to deliver the weekly follow ups for the next phase (e.g., text, phone call, zoom, or email) and every 3-week booster sessions (e.g., in person vs. zoom). 2). All quantitative data will be de-identified and exported from REDCap and analyzed in SAS or SPSS. Both the presentation and interviews will be audio-recorded and transcribed verbatim. The recordings and transcripts will be housed on a case research server and not stored directly on a hard drive. The transcripts will be de-

identified prior to data-analysis. All transcripts will be organized and coded with NVivo 12 for Mac. An audit trail will be used to track decision-making and triangulate the data. Interview data were analyzed and coded for themes using qualitative content analysis. The analysis will be inductive and begin during the data collection process to allow for ongoing modification of the interview guide. Interviews will be coded using an *in vivo* approach. Sampling will continue data redundancy is reached. 3) REDCap will be used to monitor completion of the surveys. An RA will monitor participants during the interview for aim 4 for any signs of distress. Participants will be referred to a mental health clinician or the diabetes health care provider if they have any of these concerns. If new or exacerbated health problems, such as sleep apnea or emotional distress, are detected during the study assessments, participants will be referred to their current providers (or a provider of their choice) for follow-up evaluation and possible treatment. If participants do not have an existing healthcare provider, a list of providers in the area will be provided. If safety is a concern, such as loss of consciousness with hypoglycemia during an interview session, the emergency medical response system will be activated and the RA will stay will the participant until emergency medical services arrive. 4) N/A all data will be self-report and medical records will not be queried. Participants will be asked to share their continuous glucose monitor reports or Dexcom share codes in a secure file location in REDCap and the files will be de-identified prior to analysis in SPSS or REDCap. 5) N/A no devices are being used for this study.

13.0 Study Timeline (optional)

	Pre-Screening	Visit 1	Visit 2	Visit 3	Six week Follow up
Estimated time requirement of visit					
Data Collection					
Study Procedure 1					
Study Procedure 2					
Study Procedure 3					
Phone Call Questionnaire					

14.0 ClinicalTrials.gov Information

Directions: If this study has been registered on ClinicalTrials.gov, provide the ClinicalTrials.gov identifier and the investigator/sponsor responsible for registering. If this study has not been registered on ClinicalTrials.gov, provide the rationale as to why and if/when it will be. If it does not meet the requirement for being registered on ClinicalTrials.gov, please state that.

N/A this is not a clinical trial

15.0 List of Data to be Collected

1. *Indicate what identifiers you will collect*

☒ Name

- ☐ Address *(e.g., Zip code, other geographical designation, etc.)*
- ☐ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
- ☒ Telephone number
- ☐ Fax number
- ☒ Email address
- ☐ Social security number
- ☐ Medical record number
- ☐ Health plan beneficiary number
- ☐ Account number
- ☐ Certificate/license number
- ☐ Any vehicle or other device serial
- ☐ Device identifiers or serial numbers
- ☐ Web URL
- ☐ Internet protocol (IP) address
- ☒ Finger or voice prints *(includes audio recordings)*
- ☐ Photographic images *(includes video recordings)*
- ☐ Other: Any characteristic that would uniquely identify the individual
  If other, please explain: Click here to enter text.

2. List all other data to be collected for the research study. Attach all data collection tools on the Local Site Documents page of the SpartaIRB smart form (Other Attachments). Click here to enter text.

16.0 Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, and study/safety endpoints. Aim 1: Descriptive statistics will be computed for all demographic and multi-item scales. These variables will be used to describe the sample. Study variables will be examined for marked skewness, outliers and systematic missing data. Cronbach's alphas will be computed for the multi-item scales for the full sample and separately by gender, race/ethnicity, age, and T1D duration. Aims 2-3: Correlations between sleep health, diabetes self-management, and symptoms will be assessed. Variables with a modest relationship ($r \geq .3$) will be included in a linear regression analysis. A linear regression will be run where the IV is diabetes self-management, and the DVs are glycemic control. Possible covariates will be determined. Path analysis will be done to test the mediational hypothesis (sleep health variables or distress (general and diabetes) and physical (diabetes) will mediate the effect of diabetes self-management on glycemic control) the following regression equations will be run (Baron & Kenny, 1986): To test the mediation model, the independent variable (diabetes self-management) must affect the mediator (sleep quantity, quality, or timing) in the first equation; next, the independent variable (diabetes self-management) must affect the dependent variables (glycemic control) in the second equation; and lastly the mediator (sleep quantity, quality, or timing) must affect the dependent variables in the third equation. Mediation is present if the independent variable (diabetes self-management) has no effect when the mediator (sleep quantity, quality, timing) is controlled (Baron & Kenny, 1986). Power analysis: A moderate effect size with two predictors (0.13) and 4-5 covariates would require a sample size of 150-200 participants based on a G*power 3.1 calculation. Aim 4:

We will engage 10 emerging adults and use think-aloud interviews where we will ask participants to think out loud about the program as it is delivered. An RA will prompt them to think out loud and audio record the session. We will code the data for themes using qualitative content analysis. The expected outcome of aim 4 is to identify barriers and facilitators of the proposed intervention and a protocol for the next phase of the study.

17.0 Confidentiality of Data

1. To maintain the confidentiality of the data:

   ☒ I will use a unique study identifier to code individuals' identifiable data and will store the master list separate from the study data.

   ☐ I will use a unique study identifier to code individuals' data, but it will never be linked to a master list.

   ☐ Other- please explain: Click here to enter text.

   Provide a plan to maintain or destroy identifiers once analysis of identifiable information is complete. Data will be retained for five years publication of the findings or all required final reports (e.g., progress and financial) for the project have been submitted to NIH (45 CFR Parts 75.361 and 75.364).

2. How are you storing your electronic data?

   ☒ CWRU Redcap

   ☒ CWRU Secure Research Environment (SRE)

   ☐ CWRU Box

   ☐ OnCore

   ☐ CWRU Secure Network Drive

   ☐ Other - List storage method and provide justification: Click here to enter text.

   Please note: if you're storing or entering your electronic data in any system other than an approved system listed above, please contact the CWRU IRB (cwru-irb@case.edu).

3. ☐ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following **location:** Click here to enter text.

   ☒ We will not have paper research documents.

4. Will data be shared?

   ☐ Yes

   - List the exact data elements that will be shared: Click here to enter text.
   - Describe how data will be sent: Click here to enter text.

   ☒ No

   ☐ N/A

   (Please note: if sharing data, please contact the CWRU Tech Transfer Office to ensure the proper contracts/agreements are in place.)

18.0 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?
Protected Health Information (PHI) is (1) any individually identifiable health information transmitted or maintained in a medical record, paper or electronic, or (2) designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.

☐ Yes ☒ No

If yes, indicate how HIPAA authorization will be obtained (check all that apply):

- ☐ HIPAA authorization is in the consent form
- ☐ I am receiving a Limited Data Set under a Data Use Agreement (DUA)
- ☐ Requesting a full or partial waiver of HIPAA for prescreening
  - ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*
- ☐ Requesting a full or partial waiver of HIPAA
  - ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*

19.0 Risks to Research Participants

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.
   There are no anticipated physical risks associated with this study. However, there is always a rare risk of a data breech. There is the rare potential for psychological distress related to some of the questions asked in the survey (drug, alcohol and distress questions).

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable. Click here to enter text.
   ☒ N/A
3. If applicable, describe the risks to others who are not research participants. Click here to enter text.
   ☒ N/A
4. Describe the availability of medical or psychological resources that research participants might need. Since participants are being recruited from a wider geographic area national resources such as the National Suicide Prevention Lifeline, Crisis Text Line, SAMHSA's National Helpline will be provided if they do not have a healthcare provider.
   ☒ N/A

20.0 Provisions to Protect the Privacy Interests of Research Participants

Directions: Describe the steps that will be taken to protect research participants' privacy interests. (consider issues such as physical space, proximity to other, and participant preferences)

This research is covered by a certificate of confidentiality. Effective October 1, 2017, all NIH funded research that was commenced or ongoing on or after December 13, 2016 and collects or uses identifiable, sensitive information is deemed to be issued a Certificate of Confidentiality and is therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. Under the new policy, the NIH funded researchers will no longer have to request a Certificate of Confidentiality, nor will they receive an actual certificate. No identifiers will be linked with survey responses. All data once de-identified will be maintained on a secure password protected research drive. There is the rare potential for psychological distress related to some of the questions asked in the survey (alcohol, drug use, and distress questions). Information about how to access clinic support services related to psychological risks will be provided on the consent form.

21.0 Potential Benefit to Research Participants

☐ There is potential benefit to research participants.

Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. *Do not list compensation. Click here to enter text.*

☒ There is **no** direct benefit to research participants.

If no direct benefit, state the potential benefit to society or others. *Do not list compensation.* There is no direct benefit to participants from participating in this study; however, data from this study could be used to develop meaningful interventions to improve sleep and potentially diabetes related outcomes (glycemic control, decreased symptoms, improved self-management and prevention of premature complications).

22.0 Withdrawal of Research Participants

Directions: Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent. Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

Participation is voluntary. If a choice is made not to participate, participants will be notified that it will not affect current or future relations with the University. There is no penalty or loss of benefits for not participating or for discontinuing participation. Participants will be notified that they are free to withdraw from the study at any time. **If they do decide to withdraw from the study they will be encouraged to notify the research team immediately**. The research team may also end participation in this study if instructions are not followed, scheduled responses are missed, or if safety or welfare are at risk. Partial data will still be used in the analysis.

☐ N/A

23.0 Alternatives to Participation

Directions: List other options to participation. If subjects will be compensated with extra course credit, the course instructor offering extra course credit must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research. If there are other available clinical treatments, what would be included if a

subject continued on standard of care therapy. If there is a viable alternative you must list it in the consent.

Click here to enter text.

☒ The alternative is for research subjects not to participate.

24.0 Costs to Research Participants

☒ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *please leave rest of this section blank*

1. Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs, cost of therapy, lost broken or stolen devices, etc. No associated costs

2. Explain who will be responsible for payment of provided services in the event of insurance denials. N/A

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source. No services will be covered

25.0 Research Participant Compensation

☐ There is no compensation or reimbursement for research participants – *please leave rest of this section blank*

☒ There is compensation for research participants.
Describe the schedule, payment method, and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amount, t-shirts, devices, bags, swag, etc.) Eligible participants completing the survey and diaries will receive up to two $10 Amazon gift cards (up to $20), one $10 gift card for the completion of the baseline survey and one $10 gift card for the completion of the sleep diaries (aims 1-3). Participants will receive an incentive Amazon gift card payment of $40 for participating in aim 4 (focused interview on zoom).

☐ There will be reimbursement for research participants.
Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.) Click here to enter text.

26.0 Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

- ☐ Funding agency is providing some/all payment for injury
- ☒ Funding agency is providing no payment for injury
- ☐ N/A

27.0 Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol. N/A this is a cross sectional design. Data will be collected once for aims 1-3 and once for aim 4 as this is not a repeated measures design.

2. Indicate if there will be a Data and Safety Monitoring Board or Committee:
   ☒ There will **not** be a formal Data and Safety Monitoring Board/Committee.

   ☐ There will be a formal Data and Safety Monitoring Board/Committee.

Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc. Click here to enter text.

28.0 Additional Information

If you have any additional information regarding your study not covered in the template, please include it here. Click here to enter text.

29.0 Devices

Does the study include the use of a device that is integral to the study question?

☐ **Yes –** *Answer the questions below.*
☒ **No –** *Leave the rest of this section blank.*

☐ There is an active IDE (Investigational Device Exemption) for the proposed study.
Attach an official letter of support or proof of approval which identifies the IDE holder and IDE number to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device has obtained a 501k clearance.
Attach 501k documentation to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device meets the criteria for an IDE Exemption.
Download the IDE Exemption Form from the SpartaIRB library (HRP-580) and attach to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device (and its use) is a non-significant risk device for the proposed study design.
List devices here and provide the PI's rationale for the non-significant risk device determination. Click here to enter text.

If the research involves device(s), describe your plans to use, store, handle, administer and track those device(s) to ensure that they will be used only on research participants and be used only by authorized investigators. Click here to enter text.

30.0 Community-Based Participatory Research

☒ This is **not** a community-based participatory research project – please leave the rest of this section blank

☐ This is a community-based participatory research project

Describe the involvement of the community in the design and conduct of the research.
Click here to enter text.

Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) projects, the community participates fully in all aspects of the research process.

31.0 MULTI-SITE RESEARCH (when CWRU is the IRB of Record)

Does this project have multiple sites?

☐ **Yes**

☒ **No** – please leave the rest of this section blank

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site: Click here to enter text.
2. PI of relying site: Click here to enter text.
3. Name of IRB contact: Click here to enter text.
4. Phone number of IRB contact: Click here to enter text.
5. Email address of IRB contact: Click here to enter text.

Non-Local Recruitment Methods for Multi-Site Studies

*If this is a multi-site study and research participants will be recruited by methods **not under the control of the local site** (e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. *Describe when, where, and how potential research participants will be recruited.* Click here to enter text.
2. *Describe the methods that will be used to identify potential research participants.* Click here to enter text.
3. *Describe the materials that will be used to recruit research participants.* Click here to enter text.

Multi-Site Research Communication Plan (when you are the lead investigator)

*If this is a multi-site study where you are the **lead investigator**, describe the processes to ensure communication among sites including:*

- ☐ *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*
- ☐ *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*
- ☐ *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*
- ☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*
- ☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*
- ☐ *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*
- ☐ *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

*If this is a multi-site study where you are the **lead investigator,** describe the method for communicating to engaged participant sites the following:*

1. *Problems:* Click here to enter text.
2. *Interim results:* Click here to enter text.
3. *The closure of the study:* Click here to enter text.

32.0 References

1. Suh S, Kim JH. Glycemic variability: how do we measure it and why is it important? Diabetes & metabolism journal. 2015;39(4):273-282. 2. American Diabetes Association 6. Glycemic Targets: Standards of Medical Care in Diabetes—2020. Diabetes Care. Vol 422019. 3.Foster NC, Beck RW, Miller KM, et al. State of type 1 diabetes management and outcomes from the T1D Exchange in 2016–2018. Diabetes technology & therapeutics. 2019;21(2):66-72. 4. Miller KM, Foster NC, Beck RW, et al. Current state of type 1 diabetes treatment in the U.S.: updated data from the T1D Exchange clinic registry. Diabetes care. 2015;38(6):971-978. 5. Muchmore D, Sharp M, Vaughn D. Benefits of blinded continuous glucose monitoring during a randomized clinical trial. J Diabetes Sci Technol. 2011;5(3):676-680. 6. Banarer S, Cryer PE. Sleep-related hypoglycemia-associated autonomic failure in type 1 diabetes: reduced awakening from sleep during hypoglycemia. Diabetes. 2003;52(5):1195-1203. 7. Barone MTU, Wey D, Schorr F, et al. Sleep and glycemic control in type 1 diabetes. Archives of endocrinology and metabolism. 2015;59(1):71-78. 8. Perfect MM, Elkins GR, Lyle-Lahroud T, Posey JR. Stress and quality of sleep among individuals diagnosed with diabetes. Stress and Health. 2010;26(1):61-74. 9. Clarke G, McGlinchey EL, Hein K, et al. Cognitive-behavioral treatment of insomnia and depression in adolescents: A pilot randomized trial. Behav Res Ther. 2015;69:111-118. 10. Gellis LA, Arigo D, Elliott JC. Cognitive refocusing treatment for insomnia: a randomized controlled trial in university students. Behav Ther. 2013;44(1):100-110. 11.Taylor DJ, Zimmerman MR, Gardner CE, et al. A pilot randomized controlled trial of the effects of cognitive-behavioral therapy for insomnia on sleep and daytime functioning in college students. Behav Ther. 2014;45(3):376-389. 12. Griggs S, Crawford SL. Hope, Core Self-Evaluations, Emotional Well-Being, Health-Risk

Behaviors, and Academic Performance in University Freshmen. Journal of psychosocial nursing and mental health services. 2017;55(9):33-42. 13. Griggs S, Crawford SL. Differences in hope, core self-evaluations, emotional well-being, and health risk behaviors in freshman university students. In press. 14. Griggs S, Ratner H, Hannigan J, Delaney-Black V, Chiodo L. Violence exposure, coping, and health outcomes in inner-city African American youth. Nursing Forum. In press. 15. Griggs S, Baker H, Chiodo LM. Nursing student perceptions of hope in children: A qualitative descriptive study. Nurs Forum. 2019. 16. Griggs S, Walker RK. The role of hope for adolescents with a chronic illness: an integrative review. Journal of pediatric nursing. 2016;31(4):404-421. 17. Griggs S. Hope and mental health in young adult college students: an integrative review. Journal of psychosocial nursing and mental health services. 2017;55(2):28-35. 18. Griggs S, Morris NS. Fatigue Among Adults With Type 1 Diabetes Mellitus and Implications for Self-Management: An Integrative Review. The Diabetes educator. 2018;44(4):325-339. 19. Griggs S, Redeker NS, Grey M. Sleep characteristics in young adults with type 1 diabetes. Diabetes Res Clin Pract. 2019;150:17-26. 20. Perfect MM, Beebe DW, Levine-Donnerstein D, Frye SS, Bluez GP, Quan SF. The development of a clinically relevant sleep modification protocol for youth with Type 1 diabetes. Clinical practice in pediatric psychology. 2016;4(2):227. 21. Jacobson AM, Ryan CM, Cleary PA, et al. Biomedical risk factors for decreased cognitive functioning in type 1 diabetes: an 18 year follow-up of the Diabetes Control and Complications Trial (DCCT) cohort. Diabetologia. 2011;54(2):245-255. 22. Kodl CT, Seaquist ER. Cognitive dysfunction and diabetes mellitus. Endocrine reviews. 2008;29(4):494-511. 23. Jauch-Chara K, Hallschmid M, Gais S, et al. Hypoglycemia during sleep impairs consolidation of declarative memory in type 1 diabetic and healthy humans. Diabetes care. 2007;30(8):2040-2045. 24. Jauch-Chara K, Schmid SM, Hallschmid M, Born J, Schultes B. Altered neuroendocrine sleep architecture in patients with type 1 diabetes. Diabetes care. 2008;31(6):1183-1188. 25. Adler A, Gavan MY, Tauman R, Phillip M, Shalitin S. Do children, adolescents, and young adults with type 1 diabetes have increased prevalence of sleep disorders? Pediatric diabetes. 2017;18(6):450-458. 26. Farabi SS, Broussard JL, Sippl R, et al. Sleep Extension and Continuous Glucose Monitoring in Adults with Type 1 Diabetes. SLEEP. Vol 41: NC 27513 USA; 2018. 27. Perfect MM, Frye S, Bluez GP. The Effects of a Sleep Extension Intervention on Glucose Control in Youth with Type 1 Diabetes. Diabetes. 2018;67(Supplement 1). 28. National Institute of Nursing R. Advancing science, improving lives: A vision for nursing science [16-NR-7783]. Bethesda, MD: National Institutes of Health; 2016. 29. Maahs DM, West NA, Lawrence JM, Mayer-Davis EJ. Epidemiology of type 1 diabetes. Endocrinology and metabolism clinics of North America. 2010;39(3):481-497. 30. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care. 2019;42(Supplement 1):S4-S6. 31. Nathan DM, Group DER. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. Diabetes care. 2014;37(1):9-16. 32. Varni JW, Delamater AM, Hood KK, et al. PedsQL 3.2 Diabetes Module for Children, Adolescents, and Young Adults: Reliability and Validity in Type 1 Diabetes. Diabetes care. 2018. 33. Centers for Disease Control and Prevention. National diabetes statistics report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services. 2017. 34. Fowler MJ. Microvascular and macrovascular complications of diabetes. Clinical diabetes. 2008;26(2):77-82. 35. Peters A, Laffel L, American Diabetes Association Transitions Working G. Diabetes care for emerging adults: recommendations for transition from pediatric to adult diabetes care systems: a position statement of the American Diabetes Association, with representation by the American College of

Osteopathic Family Physicians, the American Academy of Pediatrics, the American Association of Clinical Endocrinologists, the American Osteopathic Association, the Centers for Disease Control and Prevention, Children with Diabetes, The Endocrine Society, the International Society for Pediatric and Adolescent Diabetes, Juvenile Diabetes Research Foundation International, the National Diabetes Education Program, and the Pediatric Endocrine Society (formerly Lawson Wilkins Pediatric Endocrine Society). Diabetes care. 2011;34(11):2477-2485. 36. Beck J, Greenwood DA, Blanton L, et al. 2017 National standards for diabetes self-management education and support. The Diabetes educator. 2018;44(1):35-50. 37.Donga E, van Dijk M, van Dijk JG, et al. Partial sleep restriction decreases insulin sensitivity in type 1 diabetes. Diabetes care. 2010;33(7):1573-1577. 38. Farabi SS, Carley DW, Quinn L. Glucose Variations and Activity Are Strongly Coupled in Sleep and Wake in Young Adults With Type 1 Diabetes. Biological research for nursing. 2017;19(3):249-257. 39. Inkster BE, Zammitt NN, Ritchie SJ, Deary IJ, Morrison I, Frier BM. Effects of Sleep Deprivation on Hypoglycemia-Induced Cognitive Impairment and Recovery in Adults With Type 1 Diabetes. Diabetes care. 2016;39(5):750-756. 40. Owens J. Insufficient sleep in adolescents and young adults: an update on causes and consequences. Pediatrics. 2014;134(3):921. 41. Knutson KL, Van Cauter E. Associations between sleep loss and increased risk of obesity and diabetes. Annals of the New York Academy of Sciences. 2008;1129(1):287-304. 42. Kohatsu ND, Tsai R, Young T, et al. Sleep duration and body mass index in a rural population. Archives of Internal Medicine. 2006;166(16):1701-1705. 43. Spiegel K, Leproult R, Van Cauter E. Impact of sleep debt on metabolic and endocrine function. The lancet. 1999;354(9188):1435-1439. 44. Spiegel K, Tasali E, Penev P, Van Cauter E. Brief communication: sleep curtailment in healthy young men is associated with decreased leptin levels, elevated ghrelin levels, and increased hunger and appetite. Annals of Internal Medicine. 2004;141(11):846-850. 45. Leproult R, Van Cauter E. Role of sleep and sleep loss in hormonal release and metabolism. Endocrine development. 2010;17:11-21. 46. Hirshkowitz M, Whiton K, Albert SM, et al. National Sleep Foundation's sleep time duration recommendations: methodology and results summary. Sleep health. 2015;1(1):40-43. 47. Borel AL, Pepin JL, Nasse L, Baguet JP, Netter S, Benhamou PY. Short sleep duration measured by wrist actimetry is associated with deteriorated glycemic control in type 1 diabetes. Diabetes care. 2013;36(10):2902-2908. 48. Perfect MM, Patel PG, Scott RE, et al. Sleep, glucose, and daytime functioning in youth with type 1 diabetes. Sleep. 2012;35(1):81-88. 49. Patel NJ, Savin KL, Kahanda SN, et al. Sleep habits in adolescents with type 1 diabetes: Variability in sleep duration linked with glycemic control. Pediatric diabetes. 2018;19(6):1100-1106. 50. Chontong S, Saetung S, Reutrakul S. Higher sleep variability is associated with poorer glycaemic control in patients with type 1 diabetes. Journal of sleep research. 2016;25(4):438-444. 51. Larcher S, Gauchez AS, Lablanche S, Pepin JL, Benhamou PY, Borel AL. Impact of sleep behavior on glycemic control in type 1 diabetes: the role of social jetlag. European journal of endocrinology. 2016;175(5):411-419. 52. Borel AL, Benhamou PY, Baguet JP, et al. Short sleep duration is associated with a blood pressure nondipping pattern in type 1 diabetes: the DIAPASOM study. Diabetes care. 2009;32(9):1713-1715. 53. Feupe SF, Frias PF, Mednick SC, McDevitt EA, Heintzman ND. Nocturnal continuous glucose and sleep stage data in adults with type 1 diabetes in real-world conditions. Journal of diabetes science and technology. 2013;7(5):1337-1345. 54. Denic-Roberts H, Costacou T, Orchard TJ. Subjective sleep disturbances and glycemic control in adults with long-standing type 1 diabetes: The Pittsburgh's Epidemiology of Diabetes Complications study. Diabetes research and clinical practice. 2016;119:1-12. 55. Matejko B, Skupien J, Mrozińska S, et al. Factors associated with glycemic

control in adult type 1 diabetes patients treated with insulin pump therapy. Endocrine. 2015;48(1):164-169. 56. Banghoej AM, Nerild HH, Kristensen PL, et al. Obstructive sleep apnoea is frequent in patients with type 1 diabetes. Journal of diabetes and its complications. 2017;31(1):156-161. 57. Barnard K, James J, Kerr D, Adolfsson P, Runion A, Serbedzija G. Impact of chronic sleep disturbance for people living with t1 diabetes. Journal of diabetes science and technology. 2016;10(3):762-767. 58. Caruso NC, Radovanovic B, Kennedy JD, et al. Sleep, executive functioning and behaviour in children and adolescents with type 1 diabetes. Sleep medicine. 2014;15(12):1490-1499. 59. Thomas M, Sing H, Belenky G, et al. Neural basis of alertness and cognitive performance impairments during sleepiness. I. Effects of 24 h of sleep deprivation on waking human regional brain activity. Journal of sleep research. 2000;9(4):335-352. 60. Vloemans AF, Eilander MMA, Rotteveel J, et al. Youth With Type 1 Diabetes Taking Responsibility for Self-Management: The Importance of Executive Functioning in Achieving Glycemic Control: Results From the Longitudinal DINO Study. Diabetes Care. 2019;42(2):225-231. 61. Durmer JS, Dinges DF. Neurocognitive consequences of sleep deprivation. 2005;25(01):117-129. 62. McNally K, Rohan J, Pendley JS, Delamater A, Drotar D. Executive functioning, treatment adherence, and glycemic control in children with type 1 diabetes. Diabetes care. 2010;33(6):1159-1162. 63. Ismail K, Thomas SM, Maissi E, et al. Motivational enhancement therapy with and without cognitive behavior therapy to treat type 1 diabetes: a randomized trial. Annals of Internal Medicine. 2008;149(10):708-719. 64. Van der Ven NCW, Hogenelst MHE, Tromp-Wever AME, et al. Short-term effects of cognitive behavioural group training (CBGT) in adult Type 1 diabetes patients in prolonged poor glycaemic control. A randomized controlled trial. Diabetic Medicine. 2005;22(11):1619-1623. 65. Grey M, Schulman-Green D, Knafl K, Reynolds NR. A revised self-and family management framework. Nursing outlook. 2015;63(2):162-170. 66. Alvarado-Martel D, Velasco R, Sánchez-Hernández RM, Carrillo A, Nóvoa FJ, Wägner AM. Quality of life and type 1 diabetes: a study assessing patients' perceptions and self-management needs. Patient preference and adherence. 2015;9:1315. 67. Naegeli AN, Stump TE, Hayes RP. A psychometric evaluation of the Diabetes Symptom Checklist-Revised (DSC-R) cognitive distress, fatigue, hyperglycemia, and hypoglycemia subscales in patients with type 1 and type 2 diabetes. Diabetes, metabolic syndrome and obesity : targets and therapy. 2010;3:27-30. 68. Farabi SS, Quinn L, Carley DW. Validity of Actigraphy in Measurement of Sleep in Young Adults With Type 1 Diabetes. Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine. 2017;13(5):669-674. 69. Sadeh A. The role and validity of actigraphy in sleep medicine: an update. Sleep medicine reviews. 2011;15(4):259-267. 70. Kish L. Survey sampling1965. 71. Diggle P, Diggle PJ, Heagerty P, Liang K-Y, Heagerty PJ, Zeger S. Analysis of longitudinal data: Oxford University Press; 2002. 72. Czerwoniuk D, Fendler W, Walenciak L, Mlynarski W. GlyCulator: a glycemic variability calculation tool for continuous glucose monitoring data. Journal of diabetes science and technology. 2011;5(2):447-451. 73. National Institutes of H. Clinical and translational science awards consortium community engagement key function committee task force on the principles of community engagement. Principles of community engagement.2nd ed.Bethesda (MD): National Institutes of Health. 2011. 74. Neinstein A, Wong J, Look H, et al. A case study in open source innovation: developing the Tidepool Platform for interoperability in type 1 diabetes management. Journal of the American Medical Informatics Association. 2015;23(2):324-332. 75. Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. Annals of Internal Medicine. 1999;131(7):485-491. 76. Backhaus J, Junghanns K,

Broocks A, Riemann D, Hohagen F. Test–retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. Journal of psychosomatic research. 2002;53(3):737-740. 77. Buysse DJ, Reynolds CF, 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry research. 1989;28(2):193-213. 78. Yu L, Buysse DJ, Germain A, et al. Development of Short Forms From the PROMIS™ Sleep Disturbance and Sleep-Related Impairment Item Banks. Behavioral Sleep Medicine. 2012;10(1):6-24. 79. Johns MW. Reliability and factor analysis of the Epworth Sleepiness Scale. Sleep. 1992;15(4):376-381