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: January 20, 2023

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

ClinicalTrials.gov ID: NCT04975230

Please find the statistical analysis plan for this study.

Sincerely,

Stephanie Griggs, PhD, RN

IRB NUMBER: STUDY20211165
IRB APPROVAL DATE: 1/20/2023
IRB EFFECTIVE DATE: 1/20/2023
IRB EXPIRATION DATE: 10/12/2023

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 03.2021)

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

Principal Investigator: Kingman Strohl, MD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.
Type 1 Diabetes (T1D) affects 1.6 million American, and only 14% of young adults age 18-26 years achieve glycemic targets. This study aims to test resources to improve the quality of your self-management behaviors in short sleeping young adults with T1D.

Why am I being invited to take part in a research study?
You are being asked to participate in this research study because you have been identified as a young adult, aged 18-26 years with T1D.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
Each year, 1 in 8 of young adults (aged 18-26 years) with type 1 diabetes (T1D) reach their glycemic targets. Short sleep has led to decreased insulin sensitivity in studies with middle-aged adults with T1D. The purpose of this study is to the look at the effectiveness of self-management in the young adult population. This study is being conducted by a team of researchers from Case Western Reserve University and your participation in this study will help these researchers understand how to best support young adults with T1D. The researchers plan to recruit 48 participants from University Hospitals Rainbow Babies and Children's Hospital and University Hospitals Cleveland Medical Center.

Key Study Procedures
This study will collect information about you at 4 times. You will be asked to fill out questionnaires about yourself, your current sleep habits, and diabetes self-management. You will also be asked to monitor your blood sugars and wear a wrist device that monitors your activity and sleep patterns. You will be in this research study for 6 months. Participants are assigned to one of two study groups. Each study visit will take 45-60 minutes.
More detailed information about the study procedures can be found under "Detailed Study Procedures".

Key Risks
Key risks associated with your participation in this study are limited and may include: emotional distress related to sensitive questionnaires, or discomfort when using a continuous glucose monitor (CGM), wearable monitoring device, and/or a home sleep assessment device.
More detailed information about the risks of this study can be found under "Detailed Risks"

Benefits
We cannot promise there will be any benefit to you for participating in this study. However, possible benefits could include learning more about your condition and making connections between diabetes symptoms or glucose levels and activity. Your participation will help develop future self-management programs to help young adults with T1D. You will be randomly assigned to one of two conditions; each condition will likely result in positive improvements in your self-management, glycemic control, and brain function.

Alternatives to Study Participation
Participation in research is completely voluntary. You can decide to participate or not to participate. If you choose not to participate in this study, there will be no effect on your relationship with University Hospitals Rainbow Babies and Children's Hospital, University Hospitals Cleveland Medical Center, Case Western Reserve University, or your doctor. If you choose to participate, you can change your mind at any time for any reason without penalty.
The only alternative to study participation is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
As a participant in this study, your participation will involve at least 4 study visits over 6 months. Your participation will include completing questionnaires about yourself, your current sleep habits, and your diabetes self-management, completing tasks using a device and on paper (like connect the dots and reaction timing), completing a daily sleep diary, monitoring your glucose levels using a continuous glucose monitor (CGM), and wearing a wrist device that monitors your activity and sleep patterns. Some participants may choose to collect saliva and/or hair samples to look at hormone levels. Some participants may choose to complete an in-depth 1-2 day at home sleep assessment to look at disordered breathing risks.

Study Interviews

The research staff will coordinate the study interviews at times and locations convenient for you. All participants will complete 4 interviews across the study period and have weekly contact with the study staff by telephone, text or email.

The *first interview* will take place on the day you decide to participate. This interview will consist of answering about 8 questionnaires about you, like age, gender, sleep habits and activity level, complete tasks on a device and on paper, like connect the dots and reaction timing, and possibly taking a sample of your saliva (~2ml) and hair (about 35-50 strands) to measure chemicals in your body that indicate your level of certain hormones, melatonin and cortisol. You will be instructed to use the CGM and wrist device at home as well as complete a twice daily sleep journal. Some participants may complete a 1-2 night at home sleep assessment at this time. The first interview including the time to answer questions and to complete the device tasks, will take approximately 60 minutes. At the end of the first interview, a research assistant will make arrangements for the second interview.

The *second interview* will take place 14 days later. A research assistant will schedule the interview at time and location convenient for you, to download the data from the wrist device and CGM, as well as charge the devices. Your sleep data will be reviewed for patterns of sleep disordered breathing and/or sleep shorter than 7 hours on work/school days. Your participation in this study maybe discontinued by the study team if your sleep data indicate sleep disordered breathing or sleep longer than 7 hours on work/school days. If your participation is discontinued, you will be compensated for all completed interviews to date and return of the devices.
If your sleep data indicate short sleep patterns (less than 7 hours on work/school days), it is at this interview that the randomization process will occur and study condition will be assigned. You will be instructed to continue the twice-daily sleep diary and continue to use the CGM, if have own device. The second interview is expected to take about 60 minutes to complete.

Randomization
If you participate in this study, you will be assigned to one of two study groups by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned, and the study staff will tell you which group you are in. The possible study groups you could be assigned to are: a self-management intervention or a diabetes self-management education. Those participants assigned to the self-management intervention will work with a sleep coach to target specific goals. Participants assigned to the Diabetes self-management education will work with study staff to identify participant identified goals.

The *third interview* will take place 3 months later and will be at a time and location convenient for you. Prior to this visit, study staff will provide you with a wrist device and CGM (if needed) to wear for 2 weeks before the visit. During this interview you will complete about 7 questionnaires, complete tasks on a device and on paper, like connect the dots and reaction timing, complete a hemoglobin A1C via fingerstick, possibly take a sample of your saliva (~2ml) and/or hair (about 35-50 strands) to measure chemicals in your body that indicate your level of certain hormones (melatonin and cortisol), and the research assistant will download the data from the CGM. You will be instructed to continue the twice-daily sleep dairy. Some participants may complete a 1-2 night at home sleep assessment at this time. At the end of this interview, participants are expected to return the devices to the research staff. The third interview is expected to take about 60 minutes to complete.

The *fourth interview* will take place 6 months later and will be at a time and location convenient for you. During this interview you will complete about 7 questionnaires, complete tasks on a device and on paper, like connect the dots and reaction timing, and complete a hemoglobin A1C via fingerstick, possibly take a sample of your saliva (~2ml) and/or hair (about 35-50 strands) to measure chemicals in your body that indicate your level of certain hormones (melatonin and cortisol). You will be asked to download your recent CGM data. You will be provided with a wrist device and CGM (if needed) to wear for 2 weeks. You will return the device in the pre-paid mailer after the 2 weeks period.
The fourth interview is expected to take about 45 minutes to complete.

Your participation throughout the study period will include a brief weekly contact (by telephone, email or text) reminders for completion of the sleep diary and to trouble shoot devices.

You participation will also include booster session phone calls with the study staff every 4 weeks. We anticipate these sessions to take no longer than 30-40 minutes. The study staff will arrange these with you at a time convenient for you.

<u>*Salivary Biomarkers*</u>
In addition to the completion of the study questionnaires and providing glucose and activity data, the researchers wish to complete collection of salivary biomarkers at 3 time points: (1) on the day you decide to participate, (2) at the 3-month data collection, and (3) at the 6-month data collection. These salivary biomarkers will be used to help researchers understand how certain hormones, melatonin and cortisol, influence sleep patterns and rhythm.
You can participate in this research study even if you do not want to have a sample taken for salivary biomarkers. Please indicate below your choice:

- ❑ Yes, I want to have a sample for the salivary biomarkers.
- ❑ No, I do not want to have a sample for the salivary biomarkers.

Hair Cortisol

In addition to the completion of the study questionnaires and providing glucose and activity data, the researchers wish to complete collection of hair cortisol at 3 time points: (1) on the day you decide to participate, and (2) at the 3-month data collection, and (3) at the 6-month data collection. These hair cortisol samples will be used to help researchers understand how this hormone aligns with normal patterns.

You can participate in this research study even if you do not want to have a sample taken for hair cortisol. Please indicate below your choice:

- ❑ Yes, I want to have a sample for the hair cortisol.
- ❑ No, I do not want to have a sample for the hair cortisol.

Nox T3® sleep assessment

In addition to the completion of the study questionnaires and providing glucose and activity data, the researchers wish to complete an in-depth at home sleep assessment via Nox ® device, at 2 time points: (1) on the day you decide to participate, and (2) at the 3-month data collection. These in-depth sleep assessments will be used to help researchers understand how T1D relates to sleep disordered breathing risks.

You can participate in this research study even if you do not want to complete the in-depth at home sleep assessment. Please indicate below your choice:

- ❑ Yes, I want to have a sample for the in-depth at home sleep assessment.
- ❑ No, I do not want to have a sample for the in-depth at home sleep assessment.

Detailed Risks

Sensitive Questionnaires/surveys/interviews

Some of the questions we will ask may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer any question, you may skip it. If you indicate a higher distress level than normal, the RA will refer you to your primary care doctor to discuss your concerns. The study staff will also have handout for Mental Health Resources available if requested.

Breach of Confidentiality

Another risk of study participation is breach of confidentiality. This means that someone who is not listed in this form might view your data either by accident or from malicious actions they take to hack the data. However, to minimize this risk, all identifiable information about you will be securely maintained as to restrict access. All identifiable information will be destroyed at the end of the study period.

Wearable device
There are no known risks associated with wearing this watch-like device. Some people may find the device uncomfortable to wear all day. If it becomes uncomfortable or you notice redness underneath or around the area where the watch is worn, you may remove the device and wear it on the other wrist.

Continuous Glucose Monitor
There are no known risks associated with the CGM beyond the standard of care i.e., pain, bleeding, or bruising may occur at the insertion site; skin irritation or allergic reaction may occur due to adhesives or skin preparation used to clean the site. There is a possibility of infection where the skin is broken to insert the sensor, although rare. You will be instructed to monitor the CGM site for redness, bleeding or drainage.

Nox T3® assessment (optional)
There are no known risks associated with this device beyond the standard of care i.e., discomfort using a nasal cannula or RIP belts, or possible risk of infection if reusing disposable supplies. To minimize this risk, all supplies are provided by the research study and are single use only.

Consequences of lost or damaged devices
If there is accidental damage to a wearable device, you will not incur any additional costs. The consequences of a lost or damaged device include a loss of compensation for any study interviews not yet completed. You may be provided with a new CGM machine to continue to monitor your glucose levels. You will not be administered a new wrist device and your participation will be limited to CGM and survey data for the remainder of the study period.

A1C finger stick
There is generally no risk beyond the standard of care associated with the Siemens DCA Vantage HbA1C analyzer or the A1C now Professional Multi-test HbA1c System PTS diagnostics device used to monitor glycemic control.

Risk of saliva and hair sample (optional)
There is generally no pain or discomfort associated with these tests. There have been reports of infections (at the scalp site) or other adverse events related to the collection of hair samples.

Consequences of Withdrawing or Being Discontinued from the Research
Your participation in this research study is completely voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise

entitled. If you decide to participate, you may withdraw at any time for any reason without penalty. If you decide to withdraw from the study prior to its completion, it is important to let the study staff know as soon as possible. You will be asked to return any devices that the study team provided. If you choose to withdraw from the study, all data collected up to the point of withdrawal will remain a part of the study.
This study team may take you out of the study if your initial 14-day sleep data indicate sleep disordered breathing or sleep longer than 7 hours on work/school days, or if females report a positive pregnancy during the study period.
You will be compensated for all completed study interviews to date and return of study devices provided.

Reproductive Health
At each study interview, female participants will be asked the date of your last menstrual cycle to confirm you are not pregnant. If you do report pregnancy, the study team will remove you from the remainder of the study period.

Financial Information
There is no cost to you or your insurance for participation in this study. The study will pay for all devices and supplies directly associated with this research study.

You could receive up to $200 dollars for completing all study visits and returning devices provided by the study. You will be paid in electronic gift cards after each interview. If you withdraw from the study, you will only be paid for portions that you completed. The schedule for compensation is as follows:

$30 electronic gift card for Visit 1 completion.
$40 electronic gift card for Visit 2 completion.
$50 electronic gift card for Visit 3 completion.
$30 electronic gift card for return of devices (wrist device and CGM) with data.
$50 electronic gift card for Visit 4 completion.

To receive payments, you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.

Research-Related Injury

In the event you suffer a research related injury as a result of being in this study, University Hospitals is available to provide medical treatment for such injury. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of University Hospitals, the Sponsor or any of the physicians or other study personnel. If you believe that you have been injured as a result of participating in the study, please immediately contact the Principal Investigator or your study doctor at University Hospitals. If you cannot reach the Principal Investigator or your study doctor, do not delay treatment. You may seek treatment by another doctor. If you are seen or treated by a doctor other than the Principal Investigator or your study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you to assist with your treatment. Always contact the Principal Investigator or your study doctor to alert them of any treatment you receive for an injury or illness you experience during this Study.

The costs for medical treatment as a result of a research related injury may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Neither Sponsor nor University Hospitals has set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for University Hospitals or Sponsor to provide other forms of compensation (such as lost wages or other indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. To help avoid injury, it is very important to follow all study directions.

Clinically Relevant Research Results

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. You may be referred to your primary care physician for assessment.

Clinical Trial Information

U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: A description of this clinical trial will be available on http:///www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website

will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Student/Employee Rights
Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Termination of Participation
Your participation in this study may be discontinued by the investigator without your consent if your initial 14-day sleep data indicate either sleep disordered breathing, or sleep hours longer than 7 hours on work/school days, or if you come pregnant during the study period. You will be notified by the study staff of your withdrawal and any devices will be collected by study staff. You will be compensated for the interviews you completed and return of the provided study devices.

Confidentiality
All information we collect from you will be treated as confidential and kept in a safe and secure place. Your name will not be attached to any of the information we collect about you; instead, we will assign you a study number to be used on survey forms. If we are able to publish our findings, you will not be personally identified, and your name will not appear in the publication.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Future use of Identifiable Samples
It is possible that the identifiable sample(s) collected during this research project may be helpful for other project(s) as well. If this is the case, we would like to ask your permission to use your identifiable samples in these project(s). Please check the box that correctly indicates your choice. This will include use of your saliva samples.

- ❑ My identifiable samples may be used for this project only.
- ❑ My identifiable samples may be used for future research.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Nursing Research (NINR), National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of medical information in cases of medical necessity related to your care, or taking steps (including notifying authorities) to protect your or someone else from serious harm, including child abuse or neglect, or disclosing auditing information required by the agency or entity funding the research.

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Self-Management in Young Adults with Type 1 Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Kingman Strohl, MD and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on

your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: your name, age (in years), your email & mailing address, telephone number, a secondary telephone number for follow up contact, CGM medical data, and health care provider information. This PHI will be used to contact you for follow up data collection appointments and visits. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: staff from the CWRU Principal Investigator's research team; National Institute of Nursing Research (NINR), National Institutes of Health (NIH); University Hospitals, including the Center for Clinical Research and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law. It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization, you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Kingman Strohl, MD c/o Stephanie Griggs, PhD, RN at 2020 Cornell Rd., CWRU-FPB Nursing, Cleveland, Ohio 44106-4904; If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI

has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publicly available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Kingman Strohl, MD can also be contacted at 216-231-3399. The CWRU Principal Investigator, Stephanie Griggs may also be contacted at 216-368-5518. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 03.2021)

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

Principal Investigator: Kingman Strohl, MD

Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X		
Signature of Participant	Date	Time
X		
Printed Name of Participant		

X		
Signature of person obtaining informed consent	Date	Time
X		
Printed name of person obtaining informed consent		