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

Document Date: 03/16/2022

Approved by the University of Vermont Institutional Review Board on 03/17/2022

University of Vermont Consent to Participate in Research

Title of Research Project:	Does a Behavior Change Skills and Physical Activity Program Improve Self-regulation and Health Outcomes in Adolescents with Type 1 Diabetes?
Lead Investigator:	**Amy Hughes Lansing, Ph.D.**
Sites Where Research is Being Conducted	University of Vermont
Sponsor:	Vermont Center on Behavior and Health, National Institute of General Medical Science

Throughout this document “you” refers to “you or your child”.

Introduction

You are being invited to participate in a research study because you are a teenager (13-17 years old) with type 1 diabetes. This study is being conducted by the University of Vermont.

Your participation in this research study is optional. We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

Key Information to Help You Decide Whether or Not This Study Is Right for You

- This research project will help us learn more about how **behavior change skills** (setting goals, problem-solving) and **physical activity** may improve health in teens with type 1 diabetes.
- All participation in this study happens from home. There are no in-person visits.
- **In this study we will have teens with type 1 diabetes either:**
  - participate in a 12-week online and text message program to practice behavior change skills and increase physical activity or
  - continue their diabetes care as usual without participating in the 12-week program.
  - You will be assigned by chance to one of the two groups
- **At the start and end of the study all families will complete an online study visit to:**
  - complete online surveys to help us learn about how you manage challenging tasks
  - complete a fingerstick blood test, blood pressure test, weight measurement, and waist measurement to assess diabetes and heart health
  - share recent diabetes health information from glucose meter
  - receive a Garmin wristband to wear between your first visit and your second (and last) visit 12 weeks later.

- Participating in this study you might get tired or bored with the surveys or learning new behavior change skills (setting goals, problem solving). You might not like increasing your physical activity. You might need to manage changes in your glucose levels from increasing physical activity. You can stop or quit at any time. Another potential risk may be an accidental release of your personal information. Professional measures will be taken to protect your identity.
- Here's some background: We know that teens with type 1 diabetes who have experienced social or economic challenges are more likely to experience diabetes and heart health problems as older adults. Practicing behavior change skills and increasing physical activity might help teens with type 1 diabetes with diabetes management and heart health.
- Ultimately, we hope to find ways to improve health outcomes for teens with type 1 diabetes who have experienced disadvantages.

The information above is only a brief summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

Why is This Research Study Being Conducted?
The purpose of this study is to find out better ways to help teens manage diabetes and reduce cardiovascular risks associated with type 1 diabetes.

How many people will be in this study?
We expect to enroll 60 teens with type 1 diabetes in this study over the next three years.

What Is Involved In The Study?
Study participation will take a total of 3 months of your time.

If you agree to be in this study, you will be asked to:

1. After we have parent permission and teen assent, you will complete an online video-based lab appointment. We will provide you with the supplies and instructions you need to participate before your first video-based visit. The online video-based lab appointment includes:
    a. Questions about managing challenging tasks and decision making for teen and parent
    b. Taking physical measurements and a finger stick blood sample to assess your glycemic levels and cardiovascular health risks (e.g., cholesterol, blood pressure). You will be coached on how to complete these tasks by a research assistant during the video call.
        i. Physical measurements:
            1. Obtaining the dried blood spot sample will be similar to finger sticks for checking glucose. You will dot blood on a special card instead of a glucose test strip. We will provide the tools you need. You will then mail your dried blood sample to our lab.
            2. You will measure your waist and hip circumference using a measuring tape we provide following the instructions of the research assistant.

3. A blood pressure cuff (that we provide) that will squeeze your arm to find out your blood pressure. This is something similar to what happens when you visit your doctor.
4. Report your weight from a scale.
5. Report your recent glucose levels and insulin dosing.

c. You will learn how to use a Garmin to track your activity over the next 12 weeks. It will be connected to your personal phone or tablet to share your daily activity with our research team. If you do not have a personal phone or tablet, you will need to use a loaned tablet from our lab to participate and return at the end of the study. All loaned tablets will be erased upon return and no data will be recorded or collected from the device.
d. This first online visit will take 2.5 to 3 hours.

2. For the next 12 weeks you will participate in the behavior change skills training (e.g., setting goals, problem solving) and physical activity program or in your usual care. If you decide to enroll into this research study, you will be assigned by chance to one of the following groups. You can't control to which group you will be assigned. You will be assigned during your first online visit.

Behavior Change and Physical Activity Program	**Usual Care**
- Complete 8 online learning modules across 12 weeks about changing health behaviors. Each module takes about 15-20 minutes. You can do them from a personal phone, computer, or tablet. You will do some reading and some activities to help with learning and practicing behavior change (i.e., setting goals, problem-solving) with your diabetes. - Wear a Garmin daily for 12 weeks. It will be connected to a phone or tablet to share your daily activity with our research team. - Participate in 12 weeks of physical activity with personalized goal setting and support from the research team. - You will get daily text updates about your physical activity goals on weekdays. - You can earn money for meeting your physical activity goals each week. Across all 12 weeks you can earn up to $430.	- Wear a Garmin daily for 12 weeks. You can continue to use and wear any other activity tracking devices you typically use in daily life during the study. - Follow your usual diabetes treatment plan. - Engage in your usual physical activity as you wish. - Earn $.50 a day for wearing and syncing your Garmin. You can earn up to $42.

3. After 12 weeks, you will complete a second video-based lab appointment. This appointment will include the same questions and physical assessments as the first appointment. This appointment will take about 2.5-3 hours.

All study procedures will take place remotely, so it doesn't require you to travel anywhere.

What Are The Risks and Discomforts Of The Study?
The risks to you are no greater than those in everyday life with type 1 diabetes, for example, while participating in gym class, or playing sports or with peers or doing homework. We expect that most teens will find the program fun and interesting; however, it is possible that some teens may not enjoy participating. For example, learning behavior skills might be boring for some and engagement in physical activity increases the likelihood that you may experience, and need to correct low blood glucose levels. In addition, you may also experience brief discomfort from the finger stick for the dried blood spot or become upset or uncomfortable with answering questions about your health and wellbeing. Your participation is completely voluntary. Any time information is collected about you, loss of confidentiality is a possible risk. However, we are taking steps to ensure that your confidentiality is protected (see section on confidentiality on p. 4).

What Are The Benefits of Participating In The Study?
Because this program is new, we do not know for sure if it will help you with diabetes or heart health; that is what we will be studying. It is possible that those who participate in the behavior change skills and physical activity program will be helped by this program and others will not be. We also hope that the information we gain from this study may assist us in developing better ways to help other teens with diabetes and heart health.

What Other Options Are There?
Another option is to decide not to participate in this study. You always have the option of consulting with your pediatric endocrinologist about similar programs. We will provide all families with a list of national resources for both mental and diabetes health as well as physical activity support.

Are There Any Costs?
No costs are associated with participation in this study other than your time. You will need access to internet to participate.

What Is the Compensation?
Because we recognize that participation will take your time and energy you will receive $25 for the first video assessment and $50 for the second video assessment.

In addition, adolescents in the usual care group will be provided an extra incentive for wearing their Garmin, $.50/day for each day that you have Garmin data shared, up to $42. Adolescents in the intervention program group can also earn up to $430 extra incentive maximum, based upon meeting intervention goals each week as a part of the incentives program.

All compensation will be given on gift cards or cash cards provided by the study.

Can You Withdraw or Be Withdrawn From This Study?
You may discontinue your participation in this study at any time. We do not anticipate withdrawing you from the study but reserve the right to do so under some circumstances, such as your medical team discovers a medical problem or you or your parents report a glucose regulation challenge, like having persistent high or low blood glucose without correcting, that would prevent you from continuing being physically active or require greater supervision for physical activity. In this instance we will refer you to your medical provider for greater support in engaging in physical activity than is available in this intervention program. We will not use any data that we received from you if you leave the study.

What About Confidentiality?
All information collected about you will be kept confidential to the fullest extent possible by law. On all research data retained by the researchers, you will be identified by number only. Any personally identifying materials, such as this consent form, and your contact information will be stored separately from your data. All data will be electronically stored, protected by passwords known only to the research staff and on encrypted servers. All responses and data are kept strictly confidential. We will not share answers on questionnaires or research data with your parent(s) unless there is a concern about your safety. The only time we would give others information about you is if we were worried about your safety or the safety of others.

Published reports of the results of this study will not reveal any identifying information about you. De-identified data, excluding your blood sample, will be retained indefinitely and may be used in future research or be given to another investigator for future research without additional informed consent. The dried blood spot sample specimen collected from you during this study will NOT be used for future research studies or shared with other researchers for future research, even if the information identifying you are removed from the sample. Finally, we inform you that the project's research records may be reviewed by departments at the University of Vermont that are responsible for regulatory and research oversight.

Please note that email and text communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail or text could be read by a third party.

You will be required to provide your name and address each time you receive a payment. You will also be requested to provide your social security number if the amount of the payment is $100 or if the total payments from UVM are equal to or greater than $600. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork including your immigration status for payment. This information will be strictly confidential and will be used for tax withholding and reporting purposes only and will allow the University to determine your US residency for federal income tax purposes.

<u>Clinical Trials Registration</u>
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you.

At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contact Information
You may contact Dr. Hughes-Lansing, the Investigator in charge of this study, at 802-656-2670, for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been harmed as a result of your participation in this study, you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Statement of Consent
You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice.

You agree to participate in this study and you understand that you can receive a signed copy of this form.

_____ _____
Minor Providing Assent Date

_____
Name of Minor Providing Assent Printed

_____ _____
Signature of Parent/Guardian Date

_____
Name of Parent/Guardian and Participant Name Printed

_____ _____
Signature of Principal Investigator or Designee Date

_____
Name of Principal Investigator or Designee Printed

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