[Behavioral] Research Informed Consent

Title of Study: *Improving Diabetes Health in Emerging Adulthood Through an Autonomy Supportive Intervention (Phase 2)*

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Location (s): Wayne State University
3128 Integrative Biosciences, Detroit, MI 48202

Children's Hospital of Michigan
3901 Beaubien St, Detroit, MI 48201

University Health Center
4201 St Antoine St, Detroit, MI 48201

Beaumont Health
3811 W. 13 Mile Road, Royal Oak, MI 48073

Funding Source: NIDDK

Purpose

You are being asked to participate in a research study to test a newly developed treatment program to improve young adults' diabetes health. You are eligible to participate in this study because you are between 18 and 25 years old, have been diagnosed with type 1 diabetes for at least 6 months, and have an elevated HbA1c. This study is being conducted at Wayne State University, Children's Hospital of Michigan, and the University Health Center. The estimated number of study participants to be enrolled is about 320. **Please read this form and ask any questions you may have before agreeing to be in the study.**

The purpose of this research study is to test three parts of a newly developed treatment program. The first part is called My Diabetes Question List. My Diabetes Question List is a list of questions that patients with type 1 diabetes might ask their health care provider during a diabetes clinic visit. The second part is *The 3Ms,* a computer-delivered treatment program that encourages patients to make sure that their diabetes care gets done every day. This program is two sessions that occur 30 days apart. The third is text message reminders to complete daily diabetes care tasks.

Study Procedures

If you agree to take part in this research study, you will be asked to complete three study visits. These visits will take place in your home or by video conference. The first study visit will take place one month prior to an upcoming diabetes appointment. During this study visit, you will use your own or a

study-provided computer/mobile device to complete questionnaires that ask about how you care for your diabetes and other behaviors related to diabetes care. You will use a home test kit to collect a small sample of blood via a finger stick to measure your hemoglobin A1c in your home or a separate contactless visit. A research assistant will download your blood glucose monitor and review your medical chart for diabetes diagnosis and treatment information. Before the scheduled contactless visit, the research assistant will conduct a telephone screening for COVID-19 symptoms to ensure you or anyone in your household are not sick. The information collected from the COVID-19 screener will not be used for data collection or analysis. A research assistant will also help you download the treatment program software application onto your mobile phone or other device, if you have an iOS device. This study visit is expected to take about 2 - 2½ hours.

Within one week of this study visit, the intervention coordinator will assign you one of eight study groups (random assignment is like flipping a coin). Participants assigned to study groups 1-3 will receive one treatment program (My Diabetes Question List, The 3Ms, or the text message reminders). Participants assigned to study groups 4-6 will receive two parts of the treatment program. Participants assigned to study group 7 will receive all three parts of the treatment program. Participants assigned to study group 8 will not receive any of the parts of the intervention. You will continue to receive your usual diabetes medical care from your health care provider. The intervention coordinator will call you to explain which study group you are assigned to and help you get started with the program(s).

If you are assigned to a study group that includes My Diabetes Question list, approximately two weeks before your next diabetes clinic visit, you will receive a link by text message to complete your question list. Your completed question list report will be emailed to you immediately after completing the program. You will receive text message reminders from a third-party text app (e.g., GoogleVoice) to bring your diabetes question list to your next diabetes appointment.

If you are assigned to a study group that includes The 3Ms, the intervention coordinator will send you a link to complete the first session by text message within one week of your first study visit. The intervention coordinator will text you a link to complete the second session thirty days later. You will receive text message reminders to complete these sessions during the treatment period from a third-party text app (e.g., GoogleVoice).

If you are assigned to a study group that includes the text message reminder program, you will receive 30 days of one-way text message reminders. You will be given the choice of which diabetes care behaviors you want to be reminded about (blood glucose monitoring, taking insulin, counting carbohydrates, or all three). You will receive these text message reminders twice per day and be given the choice of what times of the day you want to receive your reminders.

The second and third study visits will take place 2- and 6-months after the first study visit and follow the same procedures as the first study visit. You will use your own or a study-provided computer/mobile device to complete questionnaires that ask about how you care for your diabetes and other behaviors related to diabetes care. If you are assigned to study arms 1-7, at study visit 2, you will be asked to rate how well you liked and how useful you found the different treatment programs you received. You will use a home test kit to collect a small sample of blood via a finger stick to measure your hemoglobin A1c in your home or during a separate contactless visit. A research assistant will download your blood glucose monitor while you are completing your hemoglobin A1c test and review your medical chart. Before the scheduled contactless visit, the research assistant will

conduct a telephone screening for COVID-19 symptoms to ensure you or anyone in your household are not sick. Study visits 2 and 3 are expected to take about 1 hour.

Benefits

As a participant in this study, you might benefit from setting goals and making behavior changes that could improve your diabetes care. However, these treatment programs are being tested and we cannot guarantee that you will experience any direct benefit from taking part in this study. Information from this study may benefit other people living with diabetes in the future.

Risks

As a result of taking part in this study, you may experience the following risks:

- Possible side effects from the finger stick HbA1c test include pain, bleeding, or infection at the blood draw site and, rarely, nausea or a lightheaded feeling.
- You may become tired from completing the study questionnaires. If you do become tired, you will be given a rest period or the questionnaires can be read to you. You could also become upset from answering personal questions. You may choose not to answer any of the study questions.
- Although every effort will be made to protect your study data by using secure websites to collect study information and storing this information on password protected computers, it is possible that unauthorized persons could gain access to your personal information.
- The use of video conference software poses a risk to privacy/confidentiality due to the potential of "zoombombing"/uninvited persons joining or interrupting video calls. We will make all efforts to reduce this possibility by limiting the research assistant to share their screen, only allowing the research assistant to approve participants before they may join the call, and providing a unique meeting ID and password generated for a study visit call.
- Since we will be using a third-party texting app, there is a risk for breach of confidentiality of personal information (e.g., cell phone number). All efforts will be made to protect personal information by allowing only study personnel to have access to the app/software accounts.
- During contactless home visits, there may be a risk for COVID-19 exposure. All efforts will be taken to reduce this exposure by: conducting a COVID-19 telephone screener 24 hours before the visit, sanitizing materials with sanitizing wipes, storing sanitized items in airtight plastic bags, and using personal protective equipment including face coverings and latex gloves.
- Changing your diabetes care regimen can lead to changes in your blood glucose. For example, if you increase the amount of insulin you are taking, you might experience more frequent low blood glucose levels than you currently do. If this occurs, you should follow up with your primary diabetes care provider to discuss your diabetes self-management regimen and the need to modify it. If you do not have your primary diabetes provider's contact information, a member of the research team will help you locate the information.

The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that:

- child abuse or elder abuse has possibly occurred
- you disclose illegal criminal activities, illegal substance abuse or violence

There may also be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives

The only alternative is not to participate in the study. If you would like additional information regarding diabetes care, you may talk to the medical staff in the diabetes clinic and they can assist you or provide you with more resources.

Study Costs

Participation in this study will be of no cost to you.

Compensation

For taking part in this research study, you will be paid for your time and inconvenience. You will receive a $100 gift card after completing each visit, for a total up to $300. If you are in the My Diabetes Question List or 3Ms programs, you will receive $5 for each treatment session you complete, for up to $15 more. Participants who are asked to mail their own HbA1c kit will receive $10 after the post office confirms via the tracking number that the kit was mailed.

Confidentiality

All information collected about you during the course of this research study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.] may review your records. When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

If you experience changes in your health status during the course of the study that require referral for intervention and/or support services, such as changes in the frequency of low blood sugars or symptoms of depression, anxiety, or other mental health issues, a member of the study team will notify your diabetes physician to identify local resources for you. You will be notified of this breach of confidentiality verbally and in writing with a letter outlining the referrals your physician recommended.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University, Children's Hospital of Michigan, the University Health Center, or their affiliates. Your decisions will not affect other services you are entitled to receive.

Questions

If you have any questions about this study now or in the future, you may contact Dr. April Carcone or one of her research team members at the following phone number 313-577-1057. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

_____	_____
Signature of participant	Date
_____	_____
Printed name of participant	Time
_____	_____
Signature of person obtaining consent	Date
_____	_____
Printed name of person obtaining consent	Time

IRB# 071318B3E
Jun 17, 2024 - Jun 16, 2025
APPROVAL PERIOD
WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and her research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and her research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, and medical record number.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: name (or initials), address (street address, city, state and zip code), elements of dates, telephone numbers, and medical record number.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project
- WSU's Institutional Review Boards (IRB)
- Authorized members of WSU's workforce who may need to access your information in the performance of their duties. [For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.]
- The study Sponsor or representative, including companies it hires to provide study related services, which include: NIDDK
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at any time, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____

Signature of participant Date

_____

Printed name of participant