Official Title: Addressing Disparities in Diabetes Care: Integrating Continuous Glucose Monitors and Pharmacist Medication Management for Uninsured Racial Minority Patients
NCT06643611
IRB Approval Date: 11/15/2024

Atrium Health Myers Park Internal Medicine

ADDRESSING DISPARITIES IN DIABETES CARE: INTEGRATING CGMS AND PHARMACIST MEDICATION MANAGEMENT FOR UNINSURED RACIAL MINORITY PATIENTS

Informed Consent Form to Participate in Research

Ryan Larson, PharmD, Principal Investigator

You are invited to participate in a research study. The purpose of this research is to find out if the use of a continuous glucose monitor and clinical pharmacist is helpful to improve the health of uninsured racial minority patients with type 2 diabetes. In this program, you will be provided a continuous glucose monitor for 6 months at no cost. After that time further sensors can be purchased, and the reader (if appliable) will be yours to keep.

You are invited to be in this study because you are being treated for type 2 diabetes, do not have health insurance, are a racial minority, and are a patient of Atrium Health Myers Park Internal Medicine. Your participation in this research will include visits with the pharmacist to help with managing your type 2 diabetes and completion of surveys about the program. The program will last for 6 months.

Your participation in this project is voluntary. You do not have to participate in this project if you do not want to. There may be other choices available to you. Some other choices may include receiving normal care from your physician practice. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. You can ask any questions if you need help deciding whether to join the project. The person in charge of this project is Ryan Larson, If you have any questions, suggestions, or concerns regarding this project, or you want to withdraw from the project, his contact information is: [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this study because you have you are being treated for type 2 diabetes, do not have health insurance, are a racial minority, and are a patient of Atrium Health Myers Park Internal Medicine. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

This study will take place at Atrium Health Myers Park Internal Medicine.

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00115753
Meeting Date Approved 11/15/2024
Version Valid Until: 11/4/2025

Why Is This Study Being Done?
The purpose of this research is to find out if medication management by a clinical pharmacist with the help of a continuous glucose monitor is helpful to improve the uninsured Black and Hispanic patients with type 2 diabetes receiving care at primary care practices.

Who is Sponsoring this Study?
This study is being sponsored by American Society of Health-system Pharmacists.

How Many People Will Take Part in the Study?
30 people will take part in this study.

How Long Will I Be in the Study?
Your participation in the study is planned to last for about 6 months.

What Is Involved in the Study?
Your participation in this research will involve an initial in person visit with the pharmacist to help with managing your type 2 diabetes followed by either in person visits or phone visits at least once a month. You will be provided a continuous glucose monitor for 6 months at no cost. The pharmacist will provide you information regarding how to best take care of your type 2 diabetes, help you if you have any needs about your medications, check your medical records to see if the medications you are on are correct or not, and make any changes if needed. Also, you will be asked to complete a questionnaire about your satisfaction in your diabetes treatment. The program will last for around 6 months after which you will continue to receive care from your physician.

What Are the Risks of the Study?
The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?
You may benefit from taking part in the program, but the research project will not directly benefit you.

What Are the Costs?
All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is

always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHAT ABOUT MY HEALTH INFORMATION?

In this research project, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information collected from you during this project will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with operations of Atrium Health.
We will take all the necessary steps to keep your Protected Health Information private. We will store your Protected Health Information records on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the project. This is for reasons such as to carry out the project, to determine the results of the project, to make sure the project is being done correctly, and to provide required reports. Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; the Institutional Review Board; other representatives of Atrium Health; and representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from

this project.

Any Protected Health Information collected from you in this project that is maintained in the research records will be kept for at least six years after the project is finished. At that time any research information not already in your medical record will either be destroyed, or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the system. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the project are completely finished.

You can tell Ryan Larson that you want to take away your permission to use and share your Protected Health Information by mail to [redacted].

However, if you take away permission to use your Protected Health Information you will not be able to be in the project any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research project.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or in the event of a research-related injury, contact the study investigator, Ryan Larson at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted].

Signatures

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my medical records.
- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the study doctor.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.
- I understand and agree that personal information about me will be collected in this study and from my medical records, and used and processed (manually and by computer) for the purposes of the

study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, study doctor, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

Participant signature Date Time

For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began .
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

Name of person obtaining informed consent (print)

Signature of person obtaining informed consent Date Time

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00115753
Meeting Date Approved 11/15/2024
Version Valid Until: 11/4/2025