Embedding and Evaluating Multidisciplinary Diabetes Management and Continuous Glucose Monitoring Into Primary Care for a Vulnerable Population

STUDY00006033

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NCT06015685

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 80 people who are being studied, at Emory Midtown Clinic.

Why is this study being done?

This study is being done to answer the question: Does a dedicated diabetes clinic in primary care improve patient well-being and diabetes management. You are being asked to be in this research study because you are a patient at Midtown General Internal Medicine and attend the Diabetes Clinic.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 6 months (2 more study visits after this one). The researchers will ask you to do the following: complete a survey that takes about 30 minutes today and then two more times.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Emory University
Consent to be a Research Subject

Title: Evaluating a Multi-Disciplinary Diabetes Clinic Integrated within Primary Care

IRB #: STUDY00006033

Principal Investigator: [redacted], Emory University School of Medicine, General Internal Medicine

Funding Source: Global Diabetes Center for Translational Research

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to improve diabetes management for patients at Midtown General Internal Medicine Clinic. We offer dedicated diabetes care on certain days with trained providers able to offer dedicated diabetes care. The clinic will also make sure we address other aspects of life and health that may impact an individual's ability to manage their diabetes – food insecurity, housing insecurity, knowing about healthy food, finding ways to exercise, and your mental health. The study will also train our medicine residents to be able to participate in this dedicated diabetes care.

Procedures

If you participate in the study you will be asked to complete a survey today (first visit), in 3 months, and in 6-months. The survey will take approximately 30 minutes. The survey will ask questions about your health, how you are managing your diabetes, your demographics, and your past medical history. You do not need to answer any questions you don't feel comfortable answering.

In addition, we will ask to access your medical record in the chart to obtain the following information only: weight, blood pressure, cholesterol, hemoglobin A1c.

This study is part of the diabetes clinic you are now attending. However, we are only evaluating the clinic, your care and services rendered in the clinic will not be affected in anyway by participation in the study.

Risks and Discomforts

The only foreseeable risk to you is loss of confidentiality. Your data will be kept secure in an Emory server and your name will be unlinked from the data. Instead we will use a record ID number to identify you. The file which links your name to your record ID will be kept separately and only the principal investigator will have access to that file.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about how we can improve care for patients with diabetes. The study results may be used to help others in the future.

Compensation

You will get $20 for each completed study visit given as a gift card. If you do not finish the study, you will be paid for the visits you have completed. You will receive $60 total, if you complete all study visits.

Other Options Outside this Study

If you choose not to join this study, you can get care outside of this study. You can simply choose not to participate. Your care in the diabetes clinic and Emory Midtown will not be affected in anyway

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.
The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and disclose your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:

We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

People Who will Use/Disclose Your IIHI:

The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- _Global Diabetes Center for Translational Research is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

The following people and groups will use your IIHI to make sure the research is done correctly and safely:

- Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
- Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration
- Public health agencies
- Research monitors and reviewer
- Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be disclosed to the new institution and the institution's oversight offices.

Expiration of Your Authorization
Your authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the IIHI already collected as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have

access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**