Official Title: Enhancing Telemedicine for T2D

ClinicalTrials.gov ID (NCT number): NCT06740435

Document Date: 6/12/2025

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

University of Pittsburgh

ENHANCING TELEMEDICINE CARE DELIVERY FOR ADULTS WITH COMPLEX TYPE 2 DIABETES

PRINCIPAL INVESTIGATOR:
MARGARET ZUPA, MD
ZUPAMF@PITT.EDU
OFFICE PHONE:412-586-9700
PAGER: 412-958-5791

INVITATION TO PARTICIPATE IN A RESEARCH STUDY

You are invited to take part in a research study. This form has information to help you decide whether or not you want to join the study. Please read it carefully. Your participation is completely voluntary, and you can stop participating at any time. Please ask the study team any questions you have about the study or about the information on this form before deciding whether or not to join the study.

Your doctor or other members of your healthcare team may be involved as investigators in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor, and whether or not you choose to participate will not impact the care you receive in any way.

What if I have questions about the study?
You can contact the study investigator if you have any questions about the study, concerns or complaints. Contact Principal Investigator, Dr. Zupa at 412-648-4660 or via pager 412-958-5791 or the Study coordinator at 412- 648-4660.

Who is funding this study?
Support for this study is provided by the National Institute of Diabetes and Digestive and Kidney Diseases, Award K23DK135794, which is part of the National Institutes of Health, and by the Pittsburgh Foundation.

Summary of Key Information about the Study:

- Researchers are conducting this study to see if a new approach to deliver endocrinology care for type 2 diabetes through telemedicine can help adults who have type 2 diabetes and use insulin or have multiple chronic diseases improve their care experience and diabetes management
- Participants who enroll have a 50/50 chance of being assigned to the new telemedicine intervention approach, which includes 3 telemedicine visits with an endocrinology provider over a 6-8 month period, plus extra contact with the diabetes care team between visits to help manage blood sugar, get recommended testing, and review lifestyle changes

- Participants who are not assigned to the new telemedicine intervention will receive usual telemedicine endocrinology care, including 3 visits with an endocrinology provider over 6-8 months for type 2 diabetes
- Participants will be asked to complete a survey with each visit, and some participants may be asked to take part in feedback interviews after the end of the study so that we can learn about their experiences with telemedicine diabetes care
- The risks of participating in this study are minimal and include the rare risk that a breach of confidentiality may occur.
- Your participation is completely voluntary and will not affect your ability to receive healthcare at UPMC or your primary care clinic. Even if you choose not to participate in this study, you are still able to see a UPMC Endocrinology provider through telemedicine or in-person if you wish.
- If you complete all study visits and surveys, you will be eligible to receive a total of three $50 payments, one after the first study visit, one after the mid-point visit, and one after the final visit.

Introduction:

What is the purpose of this study?

You probably know many people who have used telemedicine (internet-based video visits) to see their healthcare provider since 2020, and you may have even used telemedicine yourself to see your primary care provider or other specialty healthcare providers. Endocrinologists are doctors who specialize in treatment of diabetes and other related conditions. They are able to use telemedicine to see adults with diabetes who are not able to come to clinic in-person. This is important, since many people live very far from their closest Endocrinology clinic, or can't visit a clinic in person for another reason (if they don't have transportation, have limited mobility, or have busy work or caregiving schedules).

However, since many people started using telemedicine around the beginning of the pandemic in 2020, it has not been clear how to best support adults with type 2 diabetes who use insulin or have multiple other conditions which may make their diabetes more complicated to manage. So, the purpose of this research is to test a new approach, which was designed with input from healthcare providers and patients, to improve the care we are able to deliver to adults with type 2 diabetes who rely on telemedicine to see an Endocrinologist.

Why am I being asked to participate?

You are being asked to participate in this study because your primary care provider has identified you as someone with type 2 diabetes who uses insulin and has multiple other health conditions, and may benefit from receiving diabetes specialty are for management of type 2 diabetes.

How long will my participation in this study last?
After enrollment, we will work to schedule you for your first telemedicine visit with an endocrinology provider as soon as possible. This visit will last between 20-60 minutes. You will complete surveys about your diabetes management before that visit. You will then see your endocrinology provider additional telemedicine visits lasting between 20-60 minutes approximately 3 and 6 months after the first visit. Your total participation may last up to 12 months, depending on visit schedules, survey completion, and whether or not you are asked to participate in interviews about your experiences after all of your telemedicine visits are complete.

RESEARCH ACTIVITIES

What will happen if I join the study?
If you join the study, all participants will be asked to:

- Complete surveys before their initial telemedicine visit about their diabetes management. You will complete similar surveys at 3 months and around 6 months at the end of the study. Surveys will take place by phone or be completed using an online questionnaire, and will be conducted either by you alone or with the help of a study team member.
- You will meet with an endocrinology provider through telemedicine for approximately 30 minutes 3 times over 6-8 months
- If you are assigned to the intervention group, you will also have additional phone or video telemedicine appointments or calls between these visits with other diabetes care providers, such as diabetes educators and nurses. These calls will focus on supporting you to prepare before telemedicine visits with the endocrinology provider, making sure you have a clear understanding of next steps after a visit, helping you complete recommended testing or appointments with other providers, and supporting ongoing adjustments to diabetes medications, diet, and exercise management.
- About one quarter of enrolled participants will be asked to take part in phone or internet-based video interviews at the end of their participation in the study so that we can learn more about their experiences with telemedicine for diabetes management. The interview will last about 1 hour.
- Because we are interested in whether the diabetes telemedicine intervention affects blood sugar levels, medication prescribing, and how people receive diabetes care, we will use information from your electronic medical record to compare your Hemoglobin A1c results and medications from before and after you complete the study, as well as assess how often you interacted with members of the diabetes care team over the course of the study. See HIPAA Authorization for Disclosure of Protected Health Information, below.

How do I know if I qualify to be in this study?
You are qualified to join this study if you:

- Are between 18 and 80 years of age
- Have a diagnosis of type 2 diabetes
- Have a most recent Hemoglobin A1c level $\geq$8%

- Use insulin
- Have at least two additional chronic medical conditions, such as high blood pressure, depression, or cardiovascular disease
- Have a smartphone, tablet, or home computer with data or internet connection that allows access to video-based visits
- Reside in Pennsylvania
- Are able to provide informed consent

You should not join this study:

- Have type 1 diabetes, gestational (during pregnancy) diabetes, or other kinds of diabetes caused by medicines or damage to your pancreas
- Have dementia, cancer, or require dialysis for kidney disease
- Are already under the care of an endocrinologist
- Are pregnant or planning to become pregnant in the next 6 months
- Have seen an endocrinologist in the last year

What will I need to do if I join this study?

- **Study group assignment:**
  - After you sign up for the study, you will be randomly assigned to 1 of 2 study groups. You will have a 50% chance of being assigned to each group:
    - The new telemedicine intervention for type 2 diabetes
    - Usual telemedicine care for type 2 diabetes
- **Baseline**
  - After you've been assigned, all participants will be asked to complete a brief survey conducted by the study research assistant over the phone, or completed by you online. The survey will ask you about:
    - Your current diabetes treatment
    - Your emotional health related to your diabetes
    - Satisfaction with your current treatment
    - Completion of preventive tests such as eye and foot exams and recommended blood work
  - You will then be scheduled for an initial telemedicine visit with an endocrinology provider to discuss your diabetes treatment, priorities, and any recommended changes.
  - If you are in the new approach group, you will receive one or more phone calls before this visit to make sure you and the provider have all of the information needed to make the most of the visit. You will also receive one or more phone calls, or be scheduled for additional telemedicine appointments, with other members of the diabetes team after your visit to make sure that you have the support and tools to complete any recommended changes to diabetes treatment, diet, exercise, or complete testing or other appointments.

- Participants in the usual care arm may also receive phone calls from other diabetes care team members before or after their visit based on their endocrinology provider's usual care practices.

- **3-month and 6-month follow-up visits**
  - Participants in both study arms will have a second telemedicine visit with an endocrinology provider around 3 months after their first visit.
  - Again, participants in the new intervention arm may have additional contact with nurses, diabetes educators, or medical assistants before or after their visit to support their diabetes management.
  - Participants in the usual care arm may also receive additional contacts depending on their endocrinology provider's usual care practices.
  - You will be asked to complete another survey conducted by the study research assistant over the phone, or completed by you online. The survey will ask you about:
    - Your current diabetes treatment
    - Your emotional health related to your diabetes
    - Satisfaction with your current treatment
    - Completion of preventive tests such as eye and foot exams and recommended blood work
    - Your satisfaction with diabetes telemedicine treatment
- **Post-study interview**
  - Some participants will be asked to participate in phone or internet-based audio-only interviews after their completion of the study. The goal is to learn from your experiences with the diabetes telemedicine care you received, and find out what worked well for you and what could be improved upon for the future. We will talk about:
    - How you felt about using telemedicine to see an endocrinology provider
    - How helpful the additional contact from the diabetes care team was, if you were in the new intervention group
    - Your thoughts on how the diabetes telemedicine care impacted your diabetes management and blood sugar

- The study timeline is displayed below:

Study enrollment and consent	Baseline Survey Telemedicine visit #1	3-month Survey Telemedicine visit #2	6-month survey Telemedicine visit #3	Possible Post-study Interview with $25 payment upon completion
	New intervention group: phone calls and telemedicine visits with diabetes care team members before, after, and between visits			
	Usual care group: may receive phone calls or have additional visits with diabetes care team members based on usual practice			
	HbA1c, medications, and contact frequency from medical record collected with each visit			
	$50 payment upon completion	$50 payment upon completion	$50 payment upon completion	

What are the risks of being in this study?

Possible Risks of Participating in this Study	New Intervention	Usual Care
High or low blood sugars: As both the new intervention group and usual care group will have adjustments made to their diabetes management, it is possible that participants in either group may experience high or low blood sugars. Participants should contact their healthcare provider immediately if they experience high or low blood sugars for further instruction.	X	X
Telemedicine visits: It is possible that you may encounter difficulty using the telemedicine software to conduct video visits, which may cause discomfort. In order to protect the confidentiality of your personal health information, you should conduct telemedicine visits in a private space where only those whom you wish to attend the visit with you can see and hear you and your provider.	X	X
Study surveys and interviews: Some people may feel uncomfortable with being interviewed or with being asked to answer questions that are personal in nature. If you begin to feel uncomfortable during your interview or while completing a survey, tell your interviewer right away about how you are feeling. You can always stop the interview or survey at any time.	X	X
Confidentiality: There is a rare risk that a breach of confidentiality may occur. This includes due to use of text messaging for electronic payments, or other web-based communication and electronic data storage. We will do everything we can to prevent this from happening. If you think the confidentiality of your research information has been breached, contact either of the two investigators listed on the first page of this form.	X	X

There may be other risks or discomforts that we don't know about now. We will tell you about any important new information we learn that may relate to your willingness to continue participating in this study.

If we identify a clinically significant, unexpected disease or condition during your participation in the study, we will advise you to seek care from your primary care provider for further care of non-urgent conditions, or to call 911 for care of urgent conditions.

New information:
We will tell you about any new information that we learn that may cause you to change your mind about staying in the study.

What are the possible benefits of being in this study?
There are no guaranteed benefits from being in this study. You may benefit from this study in the following ways:

- You may have more information about how to manage your diabetes and may experience improvements in diabetes management from meeting with a diabetes specialist or other members of the diabetes healthcare team

There is no guarantee that you will receive these benefits. Your participation in this study may also help others understand how to deliver care for type 2 diabetes through telemedicine.

Who will see my personal health information? How will you protect my confidentiality?

- We will do everything we can to protect the privacy of your personal information, but confidentiality cannot be guaranteed. We will work hard to prevent a loss of privacy. We must keep the research records confidential following federal, state, and local laws. All research data collected in this study will be stored according to the privacy and security guidelines set by the U.S. Code of Federal Regulations.

- We will protect your confidentiality by assigning you a study ID number. Your research information will be labeled with your study ID number, and not with your name or other identifying information. We will permanently delete your interview recording after it has been transcribed and reviewed for accuracy. Any personally identifying information will be removed from the transcript. The information linking your study ID and your name will be kept separate from your research records. The only people who may look at your identifiable information are:
  - The investigators listed on the first page of this form and other members of the study team
  - Authorized representatives of the University of Pittsburgh Office of Research Protections. They may monitor the conduct of this study. We must keep research records for 7 years after the final project report.
  - The study sponsor, the National Institute of Diabetes and Digestive and Kidney Diseases/National Institutes of Health

- Your primary care provider and members of your diabetes healthcare team, who may also be part of the study team
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your

  identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

We will keep printed copies of all research data and signed consent forms in a locked file cabinet, behind a locked door in a secured office located on the University of Pittsburgh campus. All electronic files will be stored in folders and servers that only authorized members of the study team can access. We will do everything possible to protect the confidentiality of your electronic information. We can't guarantee, though, because no electronic storage or information sent over the internet is perfectly secure.

Study researchers will analyze the data collected from this study. If the results of this study are reported in journals or at professional meetings, you will not be identified. No information that can be used to identify you will be released or published unless required by law. Your study data may be shared with researchers doing similar research, but only after all identifying information has been removed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

When might you share my study-related information?

- At some point, your identifiers might be removed from the private information. This de-identified information may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent
- There are circumstances when the investigators might have to release identifiable information due to state law or another circumstance. Examples include:

- In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law.

- If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

- Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will it cost me or my insurance provider me anything to join this study?

There will be no cost to you or your insurance provider for the telemedicine visits or phone calls with the Endocrinologist, diabetes educator, or other diabetes study team members which you complete as part of this study.

- If you believe you have received a bill for a research-related visit, contact the study team and the UPMC office that sent the bill.

However, all medical testing, such as blood work, and all prescriptions for medications or devices, such as glucose monitors, which are "routine clinical services" that you would have received as part of your diabetes care even if you were not participating in the research study, will be billed to your health insurance company, and you will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan.

- If you do not have health insurance, you will be responsible for those costs.
- Before you complete testing or fill any prescription orders, you may want to contact your healthcare payer/insurer to see if your plan will cover the costs related to this diabetes care.. You may request more information about the costs of participating in this study and discuss this with the study team.

Will I be paid for participating this study?

- If you join this study, you will be paid with a reloadable debit card or electronic payments. We'll pay you $50 at the beginning of the study after you have completed the baseline study visit and survey, $50 at the mid-point of the study after you have completed the 3 month telemedicine visit and survey, and $50 at the end of the study after you have completed the 6-month telemedicine visit and survey. If we ask you to participate in an additional user-feedback interview, we'll pay you another $25 (possible total of $175).
- Before payments are made, a member of the study team will ask you for some personal information including your address and social security number. This information will be used for tax purposes only. All payments received for participating in a research study are taxable income, regardless of the amount. If a participant is paid $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and give a copy to the taxpayer. If you don't want to share your social security number, we will pay you a lesser amount with 24% income tax withheld. So, you would only receive 76% of the expected payment.

What are the alternatives to being in this study?

- You do not have join this study or any other research study offered to you by your healthcare provider or other staff member at the clinic where you receive care. You may choose not to be in this study and continue your current/usual care for diabetes.

What happens if I get sick or hurt while I am in this study?

- If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

What happens if I say yes now, but change my mind later and do not wish to participate in this study?

- You can quit this study at any time, including after signing this form.
- To quit the study, please contact the principal investigator listed on the first page of this form.
- Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for the purposes described above, but the study team will not collect any further information or continue to contact you.
- Your decision to withdraw will have no effect on your current or future relationship or ability to receive care from your primary care provider, UPMC Endocrinology, or other UPMC facilities or providers.

Can I be taken out of the study even if I want to continue?

The researchers may need to take you out of the study for the following reasons:

- The study team thinks it will be in your best interest not to be in the study
- The study is suspended or canceled
- You exhibit any threatening, violent or harassing behavior toward study staff
- You are put in jail or placed on parole while you are taking part in the study
- You become pregnant while you are taking part in the study

If you are withdrawn from the study, you may continue to receive care from UPMC Endocrinology, including through telemedicine, and your primary care provider as you wish.

Will I be able to access my results from this study?

- There will be no testing performed for this research study that is not part of routine clinical care. Therefore, all results (such as Hemoglobin A1c) will be included in your medical record, which you have access to. You have the right to access information that is in your medical record.

HIPAA Authorization for Disclosure of Protected Health Information

- As part of this research study, we are asking your permission to use your medical records to see if you are eligible to be in this study, to compare your earlier test results and treatments to those after participating in this study, and to support other data collected in the study, such as how frequently you had contact with the diabetes healthcare team. This permission does not expire. We will collect the following information: diagnoses, demographic information, vital signs, laboratory results, immunizations, prescriptions, past medical history, diagnostic procedures and other testing including retinal examinations, and contacts between you and your care team members including visits, phone calls, video visits, and portal messages.
- This medical record information, which includes your name, is available to members of the research team for an indefinite period.
- We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study including from your medical records once people outside UPMC or the University have viewed it.
- You can withdraw your permission to allow the research to team use your information from your medical records. You can do this by sending a request in writing to Dr. Zupa, as listed on the first page. If you do so, you will be withdrawn from this study since your medical information is a critical part. The research team will continue to use information collected from you or your records up to that point.

FDA CLINICAL TRIAL REGISTRY [21 CFR 50.25]

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

SIGNATURE SECTION

CONSENT TO PARTICIPATE

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form, I consent to participate in this research study and provide authorization to use and share my medical records. A copy of this consent form will be given to me.

_____ _____
Printed Name of Participant Date

_____
Signature of Participant

INVESTIGATOR OR DESIGNEE CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was started until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date