Study Consent

Official Title: Telemedicine for Reach, Education, Access, and Treatment- Ongoing (Treat-On) Study

ClinicalTrials.gov ID (NCT number): NCT04107935

Consent Date: 05 August 2020

University of Pittsburgh
DIABETES INSTITUTE
in partnership with UPMC

CONSENT TO PARTICIPATE IN THE
TELEMEDICINE FOR REACH, EDUCATION, ACCESS, AND TREATMENT- ONGOING (TREAT-ON) STUDY
PATIENT INFORMED CONSENT

Principal Investigator: Linda Siminerio, RN, PhD, CDE Telephone: (412) 559-0359
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Project Director, University of Pittsburgh Diabetes Institute

Jason Ng, MD
Endocrinologist

Source of Funding: National Institute of Diabetes and Digestive and Kidney Diseases

Key Information:

- The purpose of this study is to evaluate a diabetes education program provided by a diabetes educator through videoconferencing.
- This study has minimal risks.
- Your participation in this study is completely voluntary.
- You will be asked to complete four surveys over the course of 12 months.
- You will be eligible to receive up to $200 for participating in this study.

What is the purpose of the research study? The purpose of the TREAT-ON research study is to evaluate a diabetes education program provided by a diabetes educator and supported through video-conferencing. The videoconferencing program offers remote support from the educator to provide follow up on the information given during your face-to-face education visit. New ways to provide diabetes education and ongoing support are being explored knowing that people living with diabetes have situations or questions that need to be attended to between face-to-face office visits. We know that people who receive diabetes education and support are reported to have better diabetes outcomes than those who do not receive it. We want to find out what people think about using videoconferencing as a way to provide more access to ongoing support. We are interested in knowing what you think about the videoconferencing and if it helps you with your diabetes care.

How does this research study work? You are being asked to participate in this study because you have chosen to receive diabetes education use videoconferencing. As part of this study, you will be asked to complete 4 surveys over the course of 12 months. The surveys include questions about your diabetes such as how you feel about having diabetes, taking medicines, any problems that you may be having, and satisfaction in using the video-conferencing. Each survey takes about 5-15 minutes to complete. If you decide you want to participate in this study you will complete the first survey after you sign this consent form. You will also need to complete the other three surveys at approximately 3, 6 and 12 months from now. You will indicate at the end of the first survey how you would like us to contact you

to complete the surveys at 3, 6 and 12 months: at your doctor's office, by telephone, email, or mailed letter.

To learn how people are using the videoconferencing, the diabetes educator will keep a log for visit details, like how often the videoconferencing was used, how long the video visits are, what kinds of diabetes topics are talked about and any challenges with the technology. No one, other than members of our study team will be able to link your personal information to your name.

Will you be collecting any identifiable medical information? We are also requesting your authorization or permission to review your medical and health insurance records to gather information about your diabetes management while you are participating in this study. We may obtain information about the following: demographics, insurance coverage, height, weight, hemoglobin A1c, blood pressure, lipids, diabetes-related medications/prescriptions, and diabetes-related referrals and health care visits (primary care, education, emergency room and/or hospital admissions). This identifiable medical and health insurance record information will be made available to members of the research team for an indefinite period of time. We will protect your privacy and the confidentiality of your research records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical and health insurance records by contacting the principal investigator listed on the first page of this form and making the request in writing. If you withdraw, you will no longer be permitted to participate in this study. Any information obtained from you up to this point will continue to be used by the research team.

What are the possible risks and discomforts of this study? There is little risk involved with this study. There is no known physical risk and no invasive procedures are included. Participation in this study does involve the potential risk of minor psychological distress, but the study team has attempted to minimize the possibility of this risk. In addition, there is a rare risk of a breach of confidentiality (privacy), but we will do everything possible to protect your privacy. To reduce the chances of a breach of confidentiality, all researchers have been trained to protect your privacy.

Your diabetes educator is involved as an investigator in this research study. As both your diabetes educator and a research investigator, she is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another diabetes provider who is not associated with this research study. You are not under any obligation to participate in any research study offered by your diabetes educator.

Will I benefit from taking part in this study? There are no direct benefits of this research study.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study? Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed only for the purposes of this research study. You will be charged in the usual manner for any procedures performed as part of your standard medical care (care you would receive even if you were not participating in this research study).

How much will I be paid if I complete this study? If you agree to participate in this research study, you

may receive up to $200. You will receive $50 for each survey (4 surveys total) you complete and return at the designated time points described previously. All compensation is taxable income regardless of the amount. Anyone who receives $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 provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for "backup withholding;' thus you would only receive 72% of the expected payment.

Will anyone know that I am taking part in this study? All records related to your being in this study are kept strictly confidential (private). Any information that includes your identity will be stored in locked files. Your identity will not be revealed in any description or publication of this research. Results will not be shared with your health care providers who are not part of the research team and will not affect your current or future medical care at any UPMC facility.

It is possible that, in addition to the study investigators listed on the first page of this form and their study team, authorized representatives from the University of Pittsburgh Office of Research Protections (including the University of Pittsburgh IRB) may review your data (including identifiable information from medical records) for the purpose of monitoring the conduct of this study. 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 you or someone with whom you are involved is in serious danger or harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

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. This website can be searched at any time. In addition, de-identified information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

To help further protect your privacy, this study is operating under a Certificate of Confidentiality granted by National Institutes of Health (NIH). This means that the study investigators and personnel are authorized by the NIH to protect the privacy of research subjects and may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the U.S. Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). The protection afforded by the Certificate is permanent. All personally identifiable information maintained about participants in the project while the Certificate is in effect is protected in perpetuity. Research subjects may voluntarily disclose their research data or information. Subjects may disclose information to physicians or other third parties. They may also authorize in writing the investigator to release the information to insurers, employers, or other third parties. In such cases, researchers may not use the Certificate to refuse disclosure. Moreover, researchers are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or subject's threatened violence to self or others.

May I withdraw, at a future date, my permission for participation in this research study? Yes. To do so, you can contact the Principal Investigator of this study, Dr. Linda Siminerio (see phone and address listed above).

Your participation is completely voluntary. Your decision whether or not to participate in this research, or to later withdraw from it, will not affect your current or future medical care at UPMC or your relationship with the University of Pittsburgh. If you withdraw, any information collected about you up until the time you withdraw will be kept, though no additional information will be collected if you withdraw.

If you have any questions about your rights as a research participant, you may call the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office (1-866-212-2668).

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SUBJECT'S CERTIFICATION

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form will be provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the beginning of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Subject's Printed Name Date

_____

Subject's Signature

UNBIASED WITNESS INFORMATION (IF APPLICABLE)

_____ _____

Witness Printed Name Date

_____

Witness Signature

INVESTIGATOR'S 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 begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of the Person Obtaining Consent	Date