

Northwell Health

Campus: Department of Medicine, Long Island Jewish Medical Center, Northwell Health, North Shore University Hospital, North Shore University Hospital (Glen Cove), Northshore University Hospital (Manhasset), Glen Cove Family Medical Center, Southside Hospital, Nassau University Medical Center

Consent for Participation in a Research Study

Study Title: Patient and Caregiver-Centered Diabetes Tele-management Program for Hispanic/Latino Patients

Principal Investigator: Renee Pekmezaris, PhD

Sponsor: Patient Centered Outcomes Research Institute (PCORI)

About this research

You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this study is to compare two ways of managing Type 2 diabetes in the Hispanic/Latino population. One way is where you regularly visit your doctor, and the other is where you use a telehealth program in your home together with doctor's visits. We want to know if one approach is better than the other at improving overall health in Hispanics/Latino with Type 2 diabetes.
What will happen to me during the study?	A research nurse will contact you monthly to collect health data from you (for example, whether have been sick during the month). This study will compare the results of two groups of participants: The home telehealth patients will be asked to use a computerized tablet to check their glucose levels, blood pressure, pulse and weight and send the information to a nurse daily, or however often your doctor recommends. The nurse, who is located at the health system offices, will check your information to make sure that you are OK. There is also a video camera, microphone, and monitor that allows you to see and hear your nurse and for your nurse to see and hear you. Once a week, or however often your doctor recommends, you will receive a "telehealth visit" using the tablet in which a

	<p>nurse will check blood pressure, pulse, oxygen saturation, weight, and ask you about your health (detailed below).</p> <p>The group of patients that receive referrals for doctor's visits will also receive monthly phone calls from a nurse to ask about your health information (such as hospital or emergency room visits).</p>
How long will I participate?	If you choose to participate, your participation in this study will be for 12 months from the date that you agree to participate.
Will taking part expose me to risks?	<p>Regardless of whether you are in the telehealth or doctor's visit group, participating in this study does not involve any significant additional risks that you would not face during your daily routine. The use of telehealth equipment poses no substantial additional risks beyond those of using any other standard electronic equipment in the home.</p> <p><u>Interviews/Questionnaires</u></p> <p>Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study.</p> <p>As in any research study, there is a risk of your information being unintentionally revealed. However, we have a plan in place to minimize this risk</p>
Are there any benefits to participation?	Potential benefits of participants include, among other things, improved quality of life, glucose management, medication adherence, and how well you believe you are managing your diabetes. Information we learn about the management of Type 2 diabetes can help other Hispanic/Latino patients as well as patients from other racial and ethnic groups in the future.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions. You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?

The purpose of this research study is to compare two ways of managing type two diabetes: one where you regularly visit your doctor, and the other where you use a telehealth program in your home together with doctor's visits. We want to know if one approach is better than the other at improving overall health.

You are being asked to participate in this study because you qualify as a Hispanic/Latino who has been diagnosed with Type 2 diabetes, which is the health condition that we are studying.

How many people will take part in this study?

This research study hopes to enroll 224 participants, with 112 participants in each study group.

How long will you be in this study?

If you choose to take part in this study, we will monitor your health for 12 months. If you are in the telehealth group, you will be asked to answer questions about how often you are getting care and you will be asked to

attend weekly home telemonitoring visits (using the tablet) that will last about 15 minutes each for a period of 6, months. If you are in the doctor's visit group, you will be asked to answer questions about how often you are getting care.

What will happen in this research study?

If you consent to participate in this study, you will be randomly assigned to one of two groups (like flipping a coin). Randomization is a way that we make sure that people are assigned to group by chance. It is used to make sure study results are not influenced by who is in each group. In this study, you have a 50% chance of being assigned to one group or the other. This study will compare the data we collect about the health of both groups to see which type of monitoring is more beneficial to people with Type 2 diabetes.

Both groups will be asked to share their blood test results (like A1c and Lipid information) at the start of the study, at 3 months, 6 months and at the end of the study (12 months).

In addition, we will ask you to fill out the following surveys at the beginning of the study, at 6 months and at the end of the study: 1) Diabetes Distress Scale: is a questionnaire about problems that people with diabetes may experience; 2) the Diabetes – 39 quality-of-life questionnaire: has 39 questions about your quality of life; 3) Morisky 8 – Item Medication Adherence Questionnaire: asks 8 questions about taking your medication; 4) the Patient Activation Measure (PAM) has 8 questions related to your health; 5) the Social Support Survey Instrument: has 18 questions about support available to you; 6) the Diabetes Management Self-Efficacy Scale: asks about your ability to manage your diabetes; and 7) Problem Areas in Diabetes (PAID) scale: has 20 questions about problems you may have in managing your diabetes. It will take about a half hour to complete these surveys.

You are also being asked to give permission for the research team to check your medical records, and contact you, your doctor, and the nurses that are involved in your care for 12 months after you agree to be in the study in order to find out about any visits to the emergency room or hospital.

If you are chosen for the telehealth monitoring group, you will receive home monitoring equipment, which includes a computer tablet and attachments that will measure your heart rate, blood glucose, blood pressure, oxygen saturation and weight. The video camera allows the nurse to see you, and the video monitor lets you see the nurse. The tablet will have a built-in microphone and speakerphone, which will allow you and the nurse to communicate. The blood pressure cuff will monitor your blood pressure, pulse oximeter will measure the oxygen in your blood, and the digital scale will measure your body weight. For glucose measurement, you will be given a glucometer, lancet and test finger strips. Should you require any additional test finger strips, they will be provided to you free of charge by the research team. In addition, you have the right to use your own glucometer if you so desire.

Once a week, you will receive a “telehealth visit” in which a nurse will check your blood pressure, pulse, oxygen saturation, weight, and talk with you about managing your diabetes. You will interact with the nurse as if she were visiting you at home. Your equipment will send us your information daily (or as often as your doctor recommends) for six months.

Vital signs are not continuously monitored by the research nurse. Vital signs are checked within 24 hours Monday through Friday. On weekends and holidays, the nurse may not check your results until the next business day. If you feel that your vital signs are abnormal or may require medical attention, please contact your doctor immediately or go to the nearest urgent care or emergency room for an evaluation.

At each telehealth visit, the nurse will evaluate you for your blood sugar levels, check your weight and vital signs, and ask about your general health condition including:

- Medication use/compliance/changes
- Unscheduled visits to physician due to diabetes symptoms (eg., dizziness)
- Adherence with diet recommendations, food diary or log
- New symptoms which can include fatigue (tiredness), polyuria (frequent urination), polydipsia (excess thirst), polyphagia (excessive hunger)

Your health will be monitored by a nurse from your home through the internet or telephone lines. All of this equipment will be connected in your home by a trained installation technician. Your participation in this research study consists of permitting the installation of the telehealth equipment, being trained in its use, and using the equipment to communicate with a nurse.

In six months, after completion of the home telehealth monitoring portion of the study, or if you decide to drop out of the study, we will ask you and your caregiver (if you give permission) to participate in an hour long-interview. The purpose of the interview is to get richer information about your experience with telehealth home monitoring and give us a better understanding of our study results.

If you are chosen for the doctor's office referral group, you will receive monthly phone calls from a nurse asking about any illness, visits to an emergency room or hospital in the week before the call.

This study does not require you to have any additional medical procedures or treatments.

What are the risks of the research study? What could go wrong?

Regardless of whether you are in the telehealth or doctor's visit group, participating in this study does not involve more risk than what you would face during your daily routine. The use of telehealth equipment poses no substantial additional risks beyond those of using any other standard electronic equipment in the home. The telehealth nurse will advise you to keep liquids away from the equipment, as you would with any computer or telephone.

As in any research study, there is a risk of your information being shared by mistake. However, we have a plan in place to minimize this risk. In addition, some of the questions from the questionnaire could make you feel uncomfortable. If this is the case, you do not have to answer any questions that you do not want to. You can stop at any time.

Interviews/Questionnaires

Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study. If the questions make you very upset, we will help you to find a counselor.

What are the benefits of this research study?

Potential benefits of participants include, among other things, improved quality of life, glucose management, medication adherence, and how well you believe you are managing your diabetes. Information we learn about the management of Type 2 diabetes can help other Hispanic/Latino patients as well as patients from other racial and ethnic groups in the future.

Will I receive my results?

We may learn things from the study which could be important to your health or to your treatment. If this happens, you can decide whether you want this information to be provided to you. If we learn that one group does better in managing their diabetes, we can share that information with you at the end of the study. If you decide that you want this information, you may need to meet with professionals with expertise in Type 2 diabetes management to help you learn more about the research results. The study team/study will not cover the costs of any follow-up consultations or actions. Please initial one of the following options:

Yes, I want to be provided with this information.
 I do NOT want to be provided with this information.

If you do not want to take part in this research study, what are your other choices?

If you do not join this study, you have other choices for treatment. Talk to your doctor about your choices. Your other choices may include:

- Standard treatment - continue to receive standard medical care as needed.
- No treatment

Are there any costs for being in this research study?

This research study is funded by Patient Centered Outcomes Research Institute (PCORI). You will not have any added costs from being in this study. All study related visits, procedures and medications will be given to you at no cost. Neither you nor your insurance company will be billed for your participation in this research. However, costs related to your standard care will be billed as usual to your insurance company or Medicare, as applicable.

Will you receive any payments for participating in this research study?

You will be paid a total of \$100 for your time and travel expenses for being in this study. If you agree to participate in the study, you will be paid \$50.00 at that start of the study, and \$50.00 at the end of the study (total \$100 entire study). The second \$50 payment will be made at the end of the study (when we interview you).

What are your rights as a research participant?

Your participation in this project is voluntary and involves minimal risk. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time. This will have no impact on your future care at Northwell Health. At no time during the study will any member of the research team ask any information about your immigration status. The quality of your medical care will be the same, regardless of your immigration status. You have the right to withhold this information from the research team. If at any time during the research study you reveal your immigration status to any member of the research team, you will not be penalized or lose benefits to which you are entitled. Your identity and confidentiality is very important to the research team, and at no time during or after the research study will your identity and immigration status be revealed or held against. Any study information about you will be kept private and will only be given out with your permission. If the results of this study are published, your name will not be used. Your research records will be private to the extent allowed by law.

Could you be taken off the study before it is over?

Your participation in this project is voluntary. If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at the Northwell Health System. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?

You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?

If you agree to be in this study, we will collect health information that identifies you. We may collect the results of medical tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- study sponsor and/or its agents,
- other researchers,
- data safety monitoring board,
- clinical staff not involved in the study who may be involved in participant's treatment, billing,
- health insurers or payers

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services
- Representatives from Northwell Health's Human Research Protection Program (a group of people that oversee research at this institution)

- Representatives from the Patient Centered Outcomes Research Institute

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you. If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?

If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?

There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?

If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Renee Pekmezaris, Vice President
Community Health & Health Services Research
Division of Health Services Research, Department of Medicine
Center for Health Innovations and Outcomes Research
Northwell Health
600 Community Drive 4th Floor
Manhasset, New York, 1003

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?

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. You can search this website at any time.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers that have this Certificate are protected from having to share any personal information to any federal, state, or local government

agencies. For example, your information cannot be shared with anyone else who is not connected with the research except if it is required, such as reporting child abuse.

Will my information be used for research in the future?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent.

Does the investigator of this study receive money if you take part?

The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by Patient Centered Outcomes Research Institute (PCORI). If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?

If you have any questions about the study, you may call Dr. Renee Pekmezaris, the Principal Investigator) at (516-600-1414). If you have questions about side effects or injury caused by research you should call Dr. Renee Pekmezaris at (516-600-1414). If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

Printed Name of Participant

Signature of Participant

Date

Witness's Printed Name

Witness's Signature

Date

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement

I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

Signature of Investigator obtaining consent

Date

Investigator's printed name

