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Title of Research: Nurse-led app intervention to improve glycemic control among patients with insulin-treated type 2 diabetes on Medicaid
Principal Investigator: Helen Chen, PhD, RN, FNP
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RUTGERS HEALTH
School of Nursing

CONSENT TO TAKE PART IN RESEARCH

Virtual Diabetes Care (Intervention)

Title of Research: Nurse-led app intervention to improve glycemic control among patients with insulin-treated type 2 diabetes on Medicaid
Principal Investigator: Helen Chen, PhD, RN, FNP

RESEARCH SUMMARY:

- Study activities will include meeting with a research staff to learn how to use *MyChart* (a patient portal messaging app) and *mySugr* (a free diabetes app), use *mySugr* app on your phone to track your blood sugar and medication, use *MyChart* to send *mySugr* report to the clinic, get help on problem-solving by phone, get A1C tested, fill out study surveys, use *MyChart* to communicate with your healthcare team about your diabetes.
- You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your healthcare provider.
- If you are interested in learning more about the study, please continue reading, or have someone read to you the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate. You will be given a copy of this form to keep.

PURPOSE: **to use *MyChart* messaging, diabetes app, and phone help on problem-solving to support virtual diabetes care in primary care clinic**. Your time in the research will take approximately four to five hours: Your involvement will be one year, about **18 hours** total of your time.

- 4 hours per month to track your blood sugar using an app called *mySugr*
- 15 minutes per month to use *MyChart* to message study team sharing *mySugr* report
- 30 minutes per month to talk on the phone to problem-solve for diabetes
- 5 study visits and each visit is 1 to 1.5 hours per study visit to get blood test and fill out study surveys

RISKS/BENEFITS: There may be some risks from participating in this study. Your personal information could be shared by accident. The study may have benefits to you. You may enjoy learning how to use the patient portal and communicating with the nurse about your diabetes. You may feel that you are contributing to learning how to help adults manage their diabetes.

ALTERNATIVES: You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your healthcare provider.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
You are being asked to take part in research being conducted by Dr. Helen Chen who is an assistant professor in the Division of Nursing Science at School of Nursing and the Dept. of Family Medicine and Community Health at Rutgers Robert Wood Johnson Medical School, Rutgers University. Dr. Chen is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Chen may be reached at **908-466-3953** or **helen.nc.chen@rutgers.edu** or 110 Paterson St., New Brunswick, NJ 08901.

The Principal Investigator or another member of the research team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Research: National Institute of Nursing Research

Why is this research being done?
The purpose of this research is to use *MyChart* messaging, diabetes app, and phone help on problem-solving to support virtual diabetes care in primary care clinic.

Who may take part in this research and who may not?
Who may take part are:
A1C above target (>7 for age 18-64 or >8 for age 65 and older) past 12 months
Recent A1C above target (>7 for age 18-64 or >8 for age 65 and older)
Having Medicaid or dual Medicaid and Medicare or low-income based on poverty guideline
Age 18 or older with type 2 diabetes
On insulin therapy
Own and using Android or iOS smartphone for at least 6 months
Can read and write and speak English
Able to read text message on their smartphone
Uses a smartphone in ways other than emailing, texting, and making phone calls.

Who may not take part in the study are being pregnant or have impaired thinking like dementia or problem with following instruction.

Why have I been asked to take part in this research?
We are asking you to take part in a research study because you are an adult with type 2 diabetes and uses insulin to treat diabetes.

How long will the research take and how many participants will take part?
Your participation will take approximately one year to complete, about **18 hours** total of your time. We are looking for approximately 80 participants to be part of this research study.

What will I be asked to do if I take part in this research?
There is a total of 5 study visits , phone call, *MyChart* messaging, and using diabetes app (*mySugr*) to track data for diabetes. The visits will be audio and video recorded so we can create an accurate transcript of your responses for analysis.

The following is what you will do:

On the phone or in-person at a cafe or library (20-30 minutes):

1. You learn about the study, ask questions, and decide to participate or not.
2. You consent online if you agree to participant via Qualtrics survey.
3. You complete an online background survey with 30 questions.

Meeting #1 (1.5 hours):

1. In a cafe or library you will meet a trained research assistant (30 minutes):
   a. to download MyChart and *mySugr* app in your phone or table device
   b. to learn how to use *MyChart* (patient portal messaging app)
   c. to learn how to use *mySugr* (a free diabetes app)
   d. to set up your glucometer correct date and time
2. You will also complete a study survey with 132 questions (30 minutes).
3. You will go to your insurance approved lab to get A1C tested (30 minutes).

Tracking your diabetes (1 hour per week, 4 hours per month):

1. Check blood sugar at least 2x a day for 2 days a week (10 minutes 2x a day for 2 days per week = 40 minutes per week).
2. Use *mySugr* to record blood sugar numbers (5 minutes 2x a day for 2 days per week = 20 minutes per week).

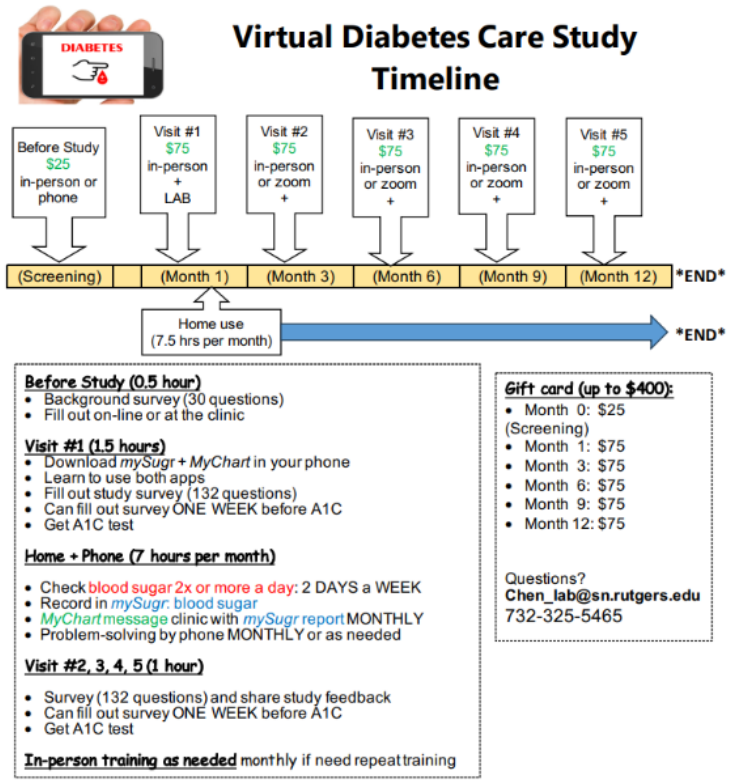
Using *MyChart* 1x a month to message study team's nurse or NP AND send in *mySugr* report (15 mins per month that is 3 hours of your time).

Attend a phone session to problem-solving diabetes once a month if you need it (15-30 minutes per month that is 6 hours total of your time).

Meeting #2 that is 3 months after meeting #1 (1 hour):
Meeting #3 that is 6 months after meeting #1 (1 hour):
Meeting #4 that is 9 months after meeting #1 (1 hour):
Meeting #5, your last visit, is 12 months after meeting #1 (1 hour):

1. In a cafe/libraryor zoom online meeting, you will complete a study survey with 132 questions (30 minutes) and give us feedback on the study (e.g., what is working, what is not working and need to change). Instead of coming to the clinic, you can complete the survey online 3 to 7 days before your A1C test.
2. You will go to your insurance approved lab to get A1C tested (30 minutes).

Below is an example of a study calendar you will have.



What are the risks of harm or discomforts I might experience if I take part in this research?
There are minimal risks from participating in this research. We will collect personal health information and there is a risk of loss of confidentiality, but we have procedures in place to minimize this risk. If you decide to quit using the app or quit the interview, your responses will NOT be saved.

When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place where your blood is drawn. However, infection is rare.

Are there any benefits to me if I choose to take part in this research?
There are no direct benefits to you. The benefits of taking part in this research may be enjoy learning how to use a diabetes app and communicating with the healthcare team about your diabetes. You may feel that you are contributing to learning how to help adults manage their diabetes. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
Your alternative is not to take part in this research.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the research. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
You will receive a total of $ 400 gift card for taking part in this study. Payment will be sent based on the schedule below, WITHIN 3 business days after you complete each study activity.

- $ 25 for completing consent form and background survey (30 questions)
- $ 75 for study visit #1 (app training, survey with 132 questions, and lab)
- $ 75 for study visit #2 (sharing feedback, survey with 132 questions, and lab)
- $ 75 for study visit #3 (sharing feedback, survey with 132 questions, and lab)
- $ 75 for study visit #4 (sharing feedback, survey with 132 questions, and lab)
- $ 75 for study visit #5 (sharing feedback, survey with 132 questions, and lab)

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Your identifiable information (e.g., your name, contact information) will NOT be stored with your responses. Instead, your responses will be assigned a participant # which will be stored separately from your identifiable information so others will not know which responses are yours. We will securely store the key code linking your responses to your identifiable information in a separate password-protected file. The key code will be destroyed after data analysis is complete.

All interview materials will be stored in a restricted folder on a protected Rutgers server. The video file will be deleted upon completion of the transcript. The audio file and transcript will be retained by the study team. The audio data will be maintained up to one year from data collection data and then deleted. Some data from this study will be kept indefinitely. Although the data will be kept, it will never be stored with any information that could be linked back to you. During analysis, any study information will always be identified in aggregate so there is never any potential of you being identified as an individual.

When we publish the results of the research or talk about it in conferences, we will not use your name. We will only combine the information from all participants and share that information. If we want to use your name, we will ask you for your permission. We may also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission. Any information about this study that could be used for future research studies or distributed to another investigator for future

research studies without additional informed consent will not include any of your personal information.

The research team may use or share your information collected or created for this research with the following people and institutions:

- The U.S. Department of Health and Human Services (DHHS) agencies
- The Rutgers University Institutional Review Board and Compliance Boards
- Representatives from Rutgers University, the Rutgers Human Research Protection Program and
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

A description of this study titled "Nurse-led app intervention to improve glycemic control among patients with insulin-treated type 2 diabetes on Medicaid" will be available on ClinicalTrials.gov, as required by U.S. 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.

Certificate of Confidentiality from the National Institutes of Health.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institute of Minority Health and Health Disparities which is funding this study. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the research is over?

After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the Research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to PI, Dr. Helen Chen. Rutgers Health School of Nursing, Division of Nursing Science, 110 Paterson St., New Brunswick, NJ 08901.

Who Can I Contact If I Have Questions?
If you have questions, concerns or complaints about the research, wish more information you can contact the Principal Investigator: Dr. Helen Chen. Rutgers Health School of Nursing, Division of Nursing Science, 110 Paterson St.,rm 317, New Brunswick, NJ 08901

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the purpose of the research and how will my information be used?
You are invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research is to help investigators answer the questions that are being asked in the research.

What information about me will be used?

- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging
- *MyChart* messages

Who may use, share or receive my information?

The research team may use or share your information collected or created for this research with the following people and institutions:

- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary for Clinical Care:
- Robert Wood Johnson Barnabas Health (RWJBH)
- Non-Rutgers Investigators on the Research Team: (Insert the affiliation and location of investigators at Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study
- Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research Is ongoing?

No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say Yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: PI, Dr. Helen Chen. Rutgers Health School of Nursing, Division of Nursing Science, 110 Paterson St., rm 317, New Brunswick, NJ 08901.

How long will my permission last?

Your permission for the use and sharing of your health information will last until end of the research.

Click on the “I Agree” button to confirm your agreement to take part in the research.
Click on the “I Disagree” button if you do not wish to take part in the research.

I Agree

I Disagree