Cover Page for ClinicalTrials.gov

Document:

Informed Consent Form

Official Study Title:

Dulce Digital-COVID Aware (DD-CA) Discharge Texting Platform for US/Mexico Border Hispanics With Diabetes + COVID-19

NCT#

NCT04591015

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March 11, 2021

CONSENT TO PARTICIPATE IN RESEARCH
Dulce Digital-COVID Aware Study
DD-CA Study

Principal Investigators: Athena Philis-Tsimikas, MD and Addie Fortmann, PhD

Study Coordinator
(or Contact Person):

Research Site(s): Scripps Whittier Diabetes Institute, 10140 Campus Point Drive, Suite 200, San Diego, CA 92121; Scripps Mercy Hospital San Diego, 4077 Fifth Avenue, San Diego, CA 92103; and Scripps Mercy Hospital Chula Vista, 435 H Street, Chula Vista, CA 91910

Sponsor: National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases (NIH/NIDDK)

This is a clinical trial (a type of research study or medical experiment). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. Be sure to ask questions about anything you do not understand.

Key Information:

What should I know about this research?

- You are being asked to be in a research study that will integrate COVID educational messaging with glucose management messaging within an easily adoptable digital texting platform.
- Your participation in this study is completely voluntary. It is your choice if you want to be in this study. This form will help you decide.
- If you agree to join, you can stop participation in the study at any time.
- If you do not agree to join, or if you decide to stop participating, you will not be penalized or lose any benefits that you had before starting the study.
- Take as much time as you need to make your choice and ask the study staff any questions.
- If you agree to join, please sign this form after you understand all of the information and your questions have been answered.

Before you start reading about this research, please read the ***California Experimental Subjects' Bill of Rights,*** which is page 2 of this form.

This study is being done at Scripps Mercy Hospital San Diego, 4077 Fifth Avenue, San Diego, CA 92103, and Scripps Mercy Hospital Chula Vista, 435 H Street, Chula Vista, CA 91910.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS*

If I am asked to consent to be a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:

1. Learn the nature and purpose of the experiment (also called "study" or "clinical trial").
2. Receive an explanation of the procedures to be followed in the study, and any drug or device to be used.
3. Receive a description of any discomforts and risks that I could experience from the study.
4. Receive an explanation of any benefits I might expect from the study.
5. Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to me.
6. Learn what medical treatment will be made available to me if I should be injured as a result of the study.
7. Ask any questions about the study or the procedures involved.
8. Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment.
9. Receive a copy of the signed and dated consent form.
10. Decide to consent or not to consent to a study without feeling forced or obligated.

If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff or need more information about my rights as a subject, I can contact the **Scripps Office for the Protection of Research Subjects**, which protects volunteers in research studies. I may telephone the Office at (858) 678-6402, 8:00 a.m. to 4:00 p.m. weekdays, or I may write to the Scripps Office for the Protection of Research Subjects, 11025 North Torrey Pines Road, Suite 200, La Jolla, CA, 92037.

By signing this document, I agree that I have read and received a copy of this Bill of Rights.

_____ _____

Signature of Subject Date

*California Health & Safety Code, Section 24172

Why is this research study being done?
In this study, we want to compare two types of treatment - Dulce Digital-COVID Aware and Usual Care. We want to see if we can:

- Reduce readmissions to the hospital,
- Improve diabetes control,
- Improve lifestyle habits such as exercise and healthy eating, and
- Increase COVID-19 awareness and education.

Our goal is to enroll 172 people in this study in one year.

Who is eligible to participate?
You can participate in this research study if you:

- Are a patient admitted to Scripps Mercy Hospital,
- Consider yourself Hispanic/Latino, of any race
- Are 18 years of age or older,
- Speak English or Spanish,
- Have type 2 diabetes and A1c $\geq$ 7% in the last 30 days, and
- Have a cellphone that can receive/send text messages.

You cannot participate in this study if you:

- Are pregnant,
- Are currently participating in another diabetes or COVID-19-related study, or
- Do not meet all eligibility criteria

What happens in this research study?
If you want to be in this study, you will be asked to sign this form. You will get a copy of this form.

We will ask you questions about you, your diabetes, your well-being, and your COVID-19 knowledge, thoughts, and experience. You will be randomly assigned (like flipping a coin) to be part of the Dulce Digital-COVID Aware group or the Usual Care group. You will be provided with a blood glucose meter, strips and lancets if your health plan does not provide this. We will draw blood to test your blood glucose (sugar).

If you are assigned to be part of the Usual Care group:

- You will receive a referral to the Scripps Diabetes Transition Program. This is a standard service that is offered to diabetes patients discharged from Scripps Mercy Hospitals. This program is designed to provide support to you after you leave the hospital.
- During the first month after you leave the hospital, a Diabetes Transition Program Health Coach will call you about once every 10 days. Most people in this program get a total of 3 calls.

- The Health Coach will help you access the information and resources you need to take care of your diabetes. The Health Coach will also support you in working through barriers to getting these resources.
- During these calls, the Health Coach will review your blood sugar readings with you, provide feedback and education to help you meet your blood sugar goals.
- You will receive a telephone call from our study staff to complete a brief survey 3 months and 6 months after you leave the hospital. The questions will be very similar to the first survey and will take about 15-20 minutes. We will ask about you, your diabetes, your well-being, and your COVID-19 knowledge, feelings and experiences. You will also be asked to come to a Scripps facility 3 months and 6 months after you leave the hospital. These visits will last about 15-30 minutes. We will draw less than one teaspoon (1-2.5mLs)of blood and measure your blood sugar [HbA1c].

If you are assigned to be part of the Dulce Digital-COVID Aware group:

- You will receive text messages about diabetes and how to take care of your diabetes and health. You will also receive text messages about how to prevent COVID-19, what to do if you have symptoms of COVID-19 and how to seek treatment if you become sick with COVID-19. You will receive 2-3 messages every day at first and the number of text messages will slowly decrease in the 6-month study period.
- You will also receive text messages that will ask you to test your blood glucose and text back your glucose reading. When you text back your result, you will receive a unique message that provides helpful tips for meeting your blood sugar goals. Study staff may encourage you to call your doctor if the tests are not in a safe range.
- You will receive a telephone call from our study staff to complete a brief survey 3 months and 6 months after you leave the hospital. The questions will be very similar to the first survey and will take about 15-20 minutes. We will ask about you, your diabetes, your well-being, and your COVID-19 knowledge, feelings and experiences. You will also be asked to come to a Scripps facility 3 months and 6 months days after you leave the hospital. These visits will last about 15-30 minutes. We will draw less than one teaspoon (1-2.5mLs)of blood and measure your blood sugar [HbA1c].

The difference between the Dulce Digital COVID-Aware group and Usual Care is that the Usual Care group will not receive text messages.

How long will I be in the study?

If you agree to be in the study, it will take less than an hour at the first visit. Calls from the Diabetes Transition Program Health Coach will take 15-30 minutes. If you are in the Dulce Digital COVID-Aware group, it will take a few minutes of your time each day to read and respond to the text messages. After 3 and 6 months, you will be asked to complete labs and a telephone survey. You will be in this study for a total of six months.

How will my information be used?

The information we get from you and the other people in this study will be put together into one file. The Dulce Digital-COVID Aware research team will then look at this information to see:

- If people were able to manage their diabetes better,

- If they made changes to lifestyle habits, like exercise and healthy eating,
- If awareness and knowledge about prevention, testing and treatment of COVID-19 increased, and
- How often people were admitted to the hospital.

These results will be compared between the Dulce Digital-COVID Aware and Usual Care groups.

What if you cannot reach me on the phone?
If we cannot reach you, we will contact the relatives or others you name when you enroll in the study to help locate you. We will also attempt to search for your information through public directories.

Is there anything experimental in this study?
None of the parts of this study are experimental. What is considered experimental is that we are putting care together in a new way to see if this helps patients with diabetes.

Will there be any risks or discomforts in the study?
You may feel uncomfortable when you are asked questions about your health and habits. You may decide to not answer any question at any time. Being in a study will involve some loss of privacy, but we will keep the information about you as private and confidential as we can. Please see the confidentiality section below to read about how we will protect your information.

The blood sampling (putting a needle into a vein) may cause some pain or a bruise on your arm, you may get dizzy, and some people get an infection.

Will I benefit from participating?
You may feel better after being in this study[drug, device, procedure], but we cannot promise that you will. Other people with diabetes may have better treatments someday. Results of this research will be shared with you and your treating physician.

Will it cost anything to be in the study?
You do not have to pay to be in this study other than transportation costs to get to and from the clinic. There may also be costs associated with the text messages used for this study. Please check with your cell phone service provided to find out what your plan covers.

Will I be paid to be in the study?
The lab tests will be paid for by the Dulce Digital-COVID Award study.

You will get a $30 gift card when you complete the survey and labs after 90 days of being part of this study and $40 gift card after you complete the survey and labs after 180 days of being part of this study. If you finish the study, you will get a total of $70 in gift cards. If you end the study early, before completing the 90-day survey and labs, then you will not receive any payment. If you end the study after completing the 90-day survey and labs but before completing the 180-day survey and labs, you will receive a $30 gift card.

What if I do not want to be in the study or I want to drop out early?
You can change your mind and quit the study at any time. If you want to leave the study, we may still use the information about you unless you ask us not to. If you want to leave the study, you should call the Dulce Digital-COVID Aware Project Coordinator at the telephone number at the top of this form.

What are my alternatives to being in the study?
You do not have to be in this study to receive regular medical care for diabetes management. You can decide not to do it.

What are my rights if I join the study?
- You may call the Project Coordinator to ask any questions about this study at any time. The telephone number is at the top of this form.
- You may choose not to be in the study or you can choose to quit any time. No matter what you do, your medical care with Scripps will not change.
- For any questions about your rights, you may call the Scripps Office for the Protection of Research Subjects at (858) 678-6402. You should also read the Experimental Subject's Bill of Rights, which is on page 2 of this form.
- You do not have to be in this study. You still have all your legal rights whether you join the study or not.
- You have the right to be told about any new information that might make you change your mind about being in this study.

What do I have to do if I join the study?
If you join this study, we ask that you:
- Follow what the research staff asks you to do.
- Keep or reschedule your study visit.

What if there is new information?
If we have new information that may change your mind about being in the study, we will tell you. We will then ask you to tell us if you want to stay in the study or not.

May I be in other research studies, while I am part of Dulce Digital-COVID Aware?
You should not participate in another research study while you are also part of Dulce Digital-COVID Aware study.

What about confidentiality?
Being in a study will involve some loss of privacy, but we will keep the information about you as private and confidential as we can. To make sure that the information about you is kept private, a code number will be given to your information; we will not use your name with the information. All information will be kept in a locked file in a locked office of the research staff.

Your name will not be used in any reports about this study. Federal agencies, such as the Office of Human Research Protection and the Institutional Review Boards of Scripps might look at results from this study and from your records. The researchers can share information without you

saying it is OK only in very special situations (for example, if they think that a person in the study or some other individual could be hurt).

For more information, please read the ***Authorization to use your Private Health Information*** at the end of this form.

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 Web site at any time.

Will Scripps Health research investigators benefit from this study?
Scripps Health research investigators and staff will be paid to do this research from the National Institutes of Health (NIH). This study will provide important information to help other patients with diabetes in the future.

Future Research
Your data (de-identified) collected for this research will not be stored and used for future research.

Questions and/or more information regarding this study
If you have any questions or would like more information right now about this research study, please ask. If you have any questions at any time while you are in the study, please contact the Project Coordinator – contact details are listed at the top of this form.

If you have questions about your rights as a participant in this study, you may contact the Scripps Office for the Protection of Research Subjects at (858) 678-6402.

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I agree to participate.

I have read and understood the explanation of the study. The study has also been explained to me by Dr. Philis-Tsimikas or a member of the research team. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel obligated to take part.

I have read the attached **Experimental Subject's Bill of Rights** and the **Authorization to use my Private Health Information** that contain some important information about research studies. I must sign this consent form, the **Experimental Subject's Bill of Rights** and the **Authorization to use my Private Health Information**. I will be given a signed copy of each to keep.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____ _____
Signature of person conducting informed consent discussion Date

_____
Role of the person conducting the consent discussion

Authorization to use your Private Health Information

Name of Study: Dulce Digital-COVID Aware Study
DD-CA Study

Principal Investigators: Athena Philis-Tsimikas, MD and Addie Fortmann, PhD

What is private health information?
Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- Your age, where you live, and how to contact you
- Information from your hospital and clinic records
- Answers to questions about your mental and physical health

Who else will see my information?
In addition to the Principal Investigator, this information may be shared with:

- the investigators and research staff named in the consent form
- government agencies, such as the US Food and drug Administration and agencies like it in other countries, or agencies of the Department of Health and Human Services, and
- Scripps committees that review research to help protect people who join research studies.

Once we have shared your information we cannot be sure that it will stay private. If you share your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will Scripps use and share my information?
Your information will be used and shared until the research is completed, which we think will be about seven years after the date you sign this form.

What if I change my mind about sharing my research information?
If you decide not to share your information anymore:

- The sponsor and the research team can continue to use any of the private information that they already have.
- You will no longer be a part of the research study.

- You will still get the same medical care that you've always had at Scripps.
- You must write to the investigator and tell her that you no longer want to share your information. Write to the investigator at:

Athena Philis-Tsimikas, MD
Addie Fortmann, PHD

Do I have the right to see and copy my research information?
You cannot see your research information while the study is going on, unless it is also being used for your health care. Once the study is over, you can ask to see any research information that is in your Medical Record that is kept at Scripps Whittier Diabetes Institute.

If you agree to share your information, you should sign this form below. You will be given a copy of this form.

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I agree to share my information as described in this form

_____
Print your name

_____ _____
Sign your name Date

If you have questions or concerns about your privacy and the use of your personal medical information, contact the investigator at the telephone number listed in the consent form.