Cover Page for ClinicalTrials.gov

Document:

Informed Consent Form

Official Study Title:

Dulce Digital-Me: An Adaptive mHealth Intervention for Underserved Hispanics with Diabetes

NCT#

NCT03130699

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August 5, 2020

CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Dulce Digital-Me: An Adaptive mHealth Intervention for Underserved Hispanics with Diabetes

Principal Investigators:
Athena Philis-Tsimikas, MD & Linda Gallo, PhD

Co-Investigators:
Addie Fortmann, PhD, Job Godino, PhD, & Scott Roesch, PhD

Project Managers:

Project Coordinator:

Research Sites:
Scripps Whittier Diabetes Institute: 10140 Campus Point Drive, Suite 200, San Diego, CA 92121
San Diego State University: South Bay Latino Research Center, 780 Bay Boulevard, Suite 200, Chula Vista, CA 91910

University of California, San Diego: 9500 Gilman Drive, La Jolla, CA 92093
Neighborhood Healthcare Clinic: 460 N Elm St, Escondido, CA 92025

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

We are asking you to be part of the "Dulce Digital-Me" study. Dulce Digital-Me is a clinical trial. This is a type of health research study. Clinical trials only include patients who want to be in the study. Please take your time to make your decision.

Before you start reading about this research, please read the California Experimental Subjects' Bill of Rights, which is page 8 of this form.

This study is being done by Scripps Health, San Diego State University, and the University of California, San Diego, in partnership with Neighborhood Healthcare.

Why is this research study being done?

In this study, we want to compare patients who receive two types of treatment - Dulce Digital-Me and Dulce Digital. We want to see if we can improve:

- Patient and provider communication;
- Diabetes control in patients and;
- Lifestyle habits such as exercise and healthy eating.

We want to recruit 414 people in this study over five years.

Who can participate?

You can be in this research study if you:

- Are a patient at Neighborhood Healthcare,
- Are Hispanic/Latino (and/or Mexican, or Chicano),
- Are 18 years of age or older,
- Have type 2 diabetes, *and*
- Have blood pressure or lab tests showing that your diabetes control could be better.

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 draw blood to test your blood glucose (sugar) and lipids (cholesterol, or fats in the blood).
- We will measure your blood pressure.
- We will measure your height and weight.
- We will ask you questions about how you take care of your diabetes, how often you take your medicine, how often you visit your doctor, and lifestyle habits (exercise and healthy eating).
- We will give you everything you need to test your blood glucose (sugar) - a blood glucose meter, strips, lancets, and control solution.
- We will explain how everything works.
- You will meet a Medical Assistant at your first visit.
- You will be randomly assigned (like flipping a coin) to be part of the Dulce Digital group or the Dulce Digital-Me group.

If you are assigned to be part of the **Dulce Digital group**:

- You will receive text messages about diabetes and how to take care of your diabetes and health. You will receive 2-3 messages every day at first. You will receive fewer messages over 6 months.
- You will be asked to answer text messages with questions about what you are eating, your exercise, and stress.

- You will need to test your blood glucose. The number of times we ask you to test your blood glucose will depend on your needs. All blood glucose readings will be sent to your healthcare team from a Telcare glucose monitor we give you to your healthcare team. A medical assistant may contact you to ask you to call your doctor if the tests are not in a good range.
- You will be given a WisePill box to help you remember to take your medicine. Every time you open the box, it will tell your healthcare team that you are taking your medicine.
- You will be asked to come to the clinic for study visits six and twelve months after your first visit. Each visit will last about 60-90 minutes. At each visit, we will draw blood and measure your labs [glucose, lipids (cholesterol)]. We will also measure your blood pressure, height and weight. We will also ask you to complete a survey. The questions will ask about how you take care of your diabetes, how often you take your medicine, how often you visit your doctor, and your health habits (exercise and health eating).

If you are assigned to be part of the **Dulce Digital-Me group**:

- You will get everything that the Dulce Digital group gets. This will include the text messages, reminders about your medicine, and nurse calls as needed. You will also get everything that you need to test your blood glucose (sugar). You will be asked to measure your blood sugar. The number of times we ask you to test your blood glucose will depend on your needs. You will also be asked to come to visits at the clinic six and twelve months after your first visit for the same measures and surveys as the Dulce Digital group.
- You will be asked to answer text messages with questions about what you are eating, your exercise, and stress.
- You will be given a WisePill box to help you remember to take your medicine. Every time you open the box, it will tell your healthcare team that you are taking your medicine.
- You will get messages with ideas and information to help you take care of your diabetes and health.
- There are two groups within the Dulce Digital-Me group. Text messages for both groups will be sent from a computer program. You will be randomly assigned to one of the following groups:
  - *Computer messages*: The computer program will use your replies to text messages and information from the WisePill box and the glucose monitor to send you text messages with ideas and information for making changes to take care of your diabetes better. You can choose how many messages you get (1-5 messages a day) and the best time for you to get the messages. If needed, you may receive a call from the medical assistant if your numbers are not in a good range.
  - *Phone Calls from a Medical Assistant*: A medical assistant will use your

responses to text messages and information from the WisePill box and the glucose monitor to call you with ideas and information making changes to take care of your diabetes better. The Medical Assistant will be calling you two times a week.

How long will I be in the study?
If you agree to be in the study, it will take about three hours at the first visit. It will take 60-90 minutes of your time at the six-month and twelve-month visits. It will take a few minutes of your time when you answer the text messages or talk to the medical assistant. You will be in this study for a total of twelve 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-Me research team will then look at this information to see:

- How often people in the study talked to and met with their doctor,
- If people were able to control their diabetes better, and
- If they made changes to lifestyle habits, like exercise and healthy eating.

These results will be compared between the Dulce Digital and Dulce Digital-Me 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. You will be asked to not eat or drink anything besides water for 8-12 hours before the blood sampling. You may take medication except those that require that you take them with food. Not eating and drinking could also make you feel dizzy. We will give you a break and a snack after the blood sampling.

Will it cost anything to be in the study?
You do not have to pay to be in this study other than anything you need to pay to get to and from the clinic.

Will I be paid to be in the study?
All labs and tests will be paid for by the Dulce Digital-Me study.

All people in the study will get a blood glucose monitor to keep at the end of the study. Everyone will also get lancets and testing strips to check blood sugar during the study.

You will get a $50 gift card when you do the survey and labs at the first visit. You will get a $25 gift card when you do the six-month survey and labs. You will get a $40 gift card after you do the twelve-month survey and labs. You can get up to $115 in gift cards if you do all of the surveys and lab visits in the study.

If you do not have your own cell phone, we will give you a cell phone to use during the study with paid text messages. No other phone services (phone calls or data) will be paid for. After the study, you can keep the cell phone if you want. The study will not pay for text messages or other cell phone service after the study is over.

If you want to use your own cell phone, we will not pay for the text messages used during the study. We will give you a gift card to pay you back for any extra costs of the text messages.

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-Me Project Manager at the telephone number at the top of this form.

What are my alternatives to being in the study?
Not being in the study is your other option. You can decide not to do it.

What are my rights if I join the study?

- You may call the Project Manager 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 at Neighborhood Healthcare will not change.
- For any questions about your rights, you may call the Scripps Office for the Protection

of Research Subjects at (858) 652-5500. You should also read the Experimental Subject's Bill of Rights, which is on page 7 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 visits.

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-Me?

You are welcome to be in another research study while you are also part of Dulce Digital-Me.

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 and/or San Diego State University and the University of California, San Diego, 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.

Will Scripps Health, San Diego State University, University of California, San Diego or the research investigators benefit from this study?
Scripps Health, San Diego State University, the University of California, San Diego and the 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.

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 Manager – 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) 652-5500.

I agree to participate.

I have read and understood the explanation of the study. The study has also been explained to me by_____. 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 the informed consent discussion	Date

Role of person named above in the research project

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) 652-5500****, 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 or Legal Representative Date

**California Health & Safety Code, Section 24172*

Authorization to use your Private Health Information

Name of Study: *Dulce Digital-Me: An Adaptive mHealth Intervention for Underserved Hispanics with Diabetes*

Principal Investigator: *Athena Philis-Tsimikas, MD*

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?

- Only the investigators named in the consent form and research staff that receives training in confidentiality procedures will see your information. In addition, Scripps committees that overview research to help protect people who join research studies may review your data if needed. Your name will not be used in any report that is written.
- If you share your information with people outside the research team, it will no longer be private.

How long will Scripps use and share my information?

Your information will be used and shared via reports and publications in aggregate (group) form (i.e., with no names or identifying information) for several years after the research is completed in 2021.

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 have always had.
- 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 10140
Campus Point Drive, Suite 200
San Diego, CA 92121

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.

****

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.