UNIVERSITY OF WASHINGTON
CONSENT FORM
Compañeros en Salud and REAL Time Continuous Glucose Monitoring

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Researcher's Statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask any questions about the study. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." Being in the study is voluntary. We will give you a copy of this form for your records.

KEY STUDY INFORMATION

The Compañeros en Salud with and without continuous glucose monitoring study will compare how a Latinx culturally informed diabetes education program in both English and Spanish works with and without a continuous glucose monitoring (CGM) device.

WHY ARE WE DOING THIS STUDY, AND WHAT WILL YOU BE ASKED TO DO IF YOU PARTICIPATE?

By doing this study, we hope to learn if the diabetes education is helpful, and if CGM makes it even more helpful. You will receive diabetes education. In addition, you may or may not use a continuous glucose monitoring (CGM) device that shows you your blood sugars in real time (RT).

WHY MIGHT YOU **NOT** WANT TO BE IN THIS STUDY?

You would need to make time to attend diabetes classes. You may prefer to just continue to work with your primary care provider for your diabetes and not receive diabetes education or CGM. You will be randomly assigned to use a real-time CGM or not. This will be decided by chance, not by you or the study team.

WHY MIGHT YOU WANT TO BE IN THIS STUDY?

Diabetes education may help improve your diabetes. Additionally, CGM may help improve your diabetes even more.

DO YOU HAVE TO TAKE PART IN THE STUDY?

No, you don't have to be in the study. If you decide to be in the study, it should be because you really want to volunteer. If you decide not to, you will not lose any services, benefits, or rights you would normally have. You will still receive treatment for your diabetes. You can choose to withdraw at any time during the study.

WHAT IF YOU WANT MORE INFORMATION?

The rest of this document gives you more information about the study, like:

- What will be done at the research visits
- The risks of the study
- Who will pay for treatment if you are injured from the study procedures
- How we will protect your privacy
- Who to talk to if you have problems, suggestions or concerns

PURPOSE OF THE STUDY

This study will provide a Latinx culturally informed diabetes education program in both English and Spanish. Some participants will also use a Continuous Glucose Monitor (CGM). We hope to learn if the diabetes education is helpful, and if CGM makes it even more helpful.

STUDY PROCEDURES

The study will be conducted through Sea Mar health clinics, University of Washington's clinics and from the community. It will include 100 people with type 2 diabetes.

You may refuse to answer any question or item in any test, inventory, questionnaire, or interview.

You will be randomly assigned to **one of two groups:**

1. To receive Compañeros en Salud diabetes education without CGM
   - You will be asked to wear a CGM that is **blinded.**
   - This means it will not show you your blood sugar numbers until the end of the study.
   - You will continue to test your blood sugar using your glucose meter as your health care provider recommends.

2. To receive Compañeros en Salud diabetes education with CGM
    - You will be asked to wear a CGM that is **unblind.**
    - This means it will show you your blood sugar numbers in real time (RT), as they are happening.

The group you are in is decided by chance (like flipping a coin). You have an equal chance of being in either group.

What is a Continuous Glucose Monitoring Device (CGM)?
Continuous glucose monitoring (CGM) is a way to measure your blood sugar, or blood glucose. It saves blood sugar numbers so you can either see them all the time (Real-Time), or you can view them later. The CGM device has a thin, flexible wire that is inserted under the skin by a skin prick. You can wear it on your stomach, arm or buttocks and it stays there for 10 days. A small plastic piece (transmitter) sits on top of the skin using medical tape to record the sugars. The whole device is about the size of a small oval cookie. The transmitter sends glucose results wirelessly to a smart phone or device for you to see either as they are happening, or later.

Also, there is a phone app called Dexcom Clarity. You can use this app to share your blood sugar numbers with the research team. You can also choose to share with a family member but only if you want to. To share the blood sugars, your family member will also need to use the app and have your “OK” to see them.

We will give you all the CGM supplies you will need. You will have a pre-addressed postage-paid envelope to mail back the device at the end of 10 days. If you are unable to mail it, a Patient Navigator (PN) formerly known as Community Health Worker (CHW) or health educator may come by your home to pick it up or you may bring it to clinic.

Sometimes a CGM might accidentally fall off or stop working before the end of the 10 days. If this happens within the first 3 days, we will give you a new CGM.

What is the time period for the study and what do I need to do?

Your participation in the study will be for 6 months **with the following visits:**

- 3 scheduled research visits (1-1.5 hours each),
- 1 scheduled Patient Navigator or health educator check-in and teaching (1-1.5 hours and this may be coupled to research visit 1)
- 12 diabetes classes (1-1.5 hours each, offered at different times in English and Spanish) for a total study participation time of about 25 hours.

If you wish to participate in this study, we will ask you to read and sign this consent document before any data is collected. The research visits will take place through telemedicine in your home or, if you prefer, at your local Sea Mar or University of Washington Clinic. Or you can choose to do part of the visits at home and part at a clinic.

If you sign this form online, a copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, or if you wish to withdraw your consent, please contact the researcher listed on page 1 of this consent form.

We will also ask you to provide contact information (phone number, address, email, and family and/or friends' contact information). We will use this information to contact you about the classes and data collection visits.

After signing this informed consent, we will do a fingerstick to measure your hemoglobin A1C. This blood test shows your average blood sugar level over the past 2-3 months (unless you already had one in the last 2 weeks). If you are female, we will do a urine pregnancy test. (This study will not include pregnant women). If this visit is not in person we may ask you to go the lab for a blood draw for this test and urine test. You can't be in the study if your A1C is less than 8.0 or you are pregnant. If you do become pregnant, you will continue your diabetes and pregnancy care with your health care provider, and you will not continue in the study.

1. Visit 1: Screening and Data Collection

- Takes place 2-4 weeks before the first diabetes class
- Will take 1-1.5 hours to complete
- We will measure your height, weight, blood pressure and waist circumference (using a measuring tape around your waist).
- We will ask you questions about your diabetes, your health, and your habits.
- We will randomly assign you to the diabetes classes with or without CGM.
- We will tell you the dates of the 12 weekly classes (in Spanish or English).
- We will ask you to use your phone app to count your steps and measure how much you walk. If you do not have a phone app, we will give you a pedometer. We will ask you to wear the pedometer or keep your phone on you while you are awake as much as possible during the study.

- We will give you a $50.00 gift card at the end of the visit.

2. Patient Navigator (PN) / Health Educator (HE) or Study Personnel follow-up

On the same day as the first study visit or another time in your home or at the local clinic but before you start diabetes classes, a Patient Navigator (PN) or health educator/(HE) will help you with the items below.

Ensure you have Zoom and internet access. If you do not have internet access at home we will provide you with a device with internet access to use during the 12-week classes. They will

also show you how to insert the CGM. They will help you solve common issues that people sometimes have when using CGMs.

If you are in the real-time (RT-CGM) group, the PN /HE will help you install the Clarity app on your phone that you will need to use the device or show you how to use the receiver device. They will show you how to share it with family members if you choose to. The PN/HE will also talk with you about how food and activity affect your blood sugar. They will teach you how to use the CGM to see your blood sugar levels, and help you understand what the CGM numbers mean.

The PN /HE will give you a food and activity log. If you choose a telemedicine/Zoom visit, the PN/HE may ask if they can see you in-person to do some measurements (A1C and body measurements).

After visit one, all participants in both groups will wear a blinded CGM for 10 days. This means you will not see your blood sugar numbers. You will then return the CGM at the first diabetes class in person, or you can mail it back.

If you do not receive the RT-CGM you will continue to monitor your sugars as recommended by your doctor by fingerstick.

3. Education Classes: Compañeros en Salud Classes

Next you will attend weekly diabetes education classes for 12 weeks.

These will be group classes once a week via telehealth/Zoom or at a Sea Mar classroom. You will be in the class with other people who have type 2 diabetes. We will ask you to attend all 12 classes. Each class will last up to 1-1.5 hours. We will give you all the materials for each class.

These classes will use the Zoom platform. Classes will be recorded so that you may watch them later. Before you join each class, you will see a message that says the session will be recorded. Also, while we encourage you to appear on camera during the classes, you do not have to. You can choose to show or hide your camera.

At the end of the first class, those that are in the the RT-CGM after the first class will receive 15-30minutes education on food and activity and how to see what is happening to the sugars by the CGM. They will be encouraged to start the RT-CGM at the end of the first class and study personnel or the PN /HE may check on them the next day to ensure they have no problems with using the RT-CGM

4. Study Visit 2

At the end of class 12, we will:

- Ask you questions about your diabetes
- Measure an A1C to see how your blood sugar levels have been

- Do the same body measurements as we did at your first visit.
- Give you a $50.00 gift card at the end of the visit.

- If you are not in the real-time CGM (RT-CGM) group:
  - You will wear a blinded one more time CGM for 10 days starting 3 days prior to class 11 and returning after 10 days. If you forget you can start it as soon as you remember
  - The PN /HE or research staff will help you insert the blinded CGM via telemedicine or in person if needed.
  - You will not see your blood sugars

- If you are in the real-time CGM (RT-CGM) group:
  - You will wear the RT-CGM one more time for 10 days 3 days prior to session 11 or if you forget as soon as you remember.
  - You will see your blood sugars as they happen.

After study visit two you will continue to work on your diabetes with your primary care doctor. The diabetes classes and use of RT-CGM will be over. You should ask your doctor if you have any questions about your diabetes.

5. Study visit 3

This visit will be 3 months after the last diabetes class.

We will ask everyone to wear a blind sensor for 10 days. This will be the last time you will wear it. We will ask you the same questions we did at your other visits. We will also test A1C and body measurements.

When do you wear the RT-CGM?
If you are in the real-time continuous glucose monitoring device (RT-CGM) group, after your first diabetes class, you will start wearing the device for a total of five 10-day cycles of use of RT-CGM. You will receive 2 extra sensors in case the CGM falls off early.

- Start wearing the RT-CGM once you complete your first diabetes class. Wear for 10 days.
- Then leave off for 7 days
- Then wear again for 10 days
- The cycle is to wear for 10 days then off for 7 days then wear for 10 days until you have completed a total of 50 days (5 sessions) of wearing the sensor.
- The goal is to start the last sensor 3 days prior to session 11 and wear for the last 10 days.

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This table shows the visit schedule, information to be collected, and CGM wear schedule for each group.

Visit Type	Screening and Visit 1	Visit 2	Visit 3
Study week	Week Zero	Week 12*	Week 24*
Read and sign the Informed consent	**X**		
Emergency contact	**X**		
Urine Pregnancy test (Females)	**X**		
Demographics	**X**	**X**	**X**
Medications, medical history	**X**	**X**	**X**
Questionnaires	**X**	**X**	**X**
HbA1C fingerstick blood test	**X**	**X**	**X**
Blood Pressure, pulse, height, weight, waist measurements	**X**	**X**	**X**
Pedometer App for 10 days	**X**	**X**	**X**
Patient Navigator visit	**X**		
Random assignment to CGM group	**X**		
Blinded CGM Group	Blinded CGM 10 days	Blinded CGM 10 days	Blinded CGM 10 days
RT-CGM Group	Blinded CGM 10 days	**RT-CGM** (Five cycles for 10 days on, seven days off)	Blinded CGM 10 days
12-weeks diabetes classes		**X**	**X**
Family member survey (both groups)	**X**	**X**	
$50 gift card	**X**	**X**	**X**

* Within 2 weeks of this date.

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After study completion at the end of visit 3, we will offer to control/blinded group participants who express an interest, the possibility to wear 3 Dexcom Real Time sensors as supplies allow. You will not have to pay for these sensors. Data collected from these devices will not be used in the study, and the study team will not have access to this data. If you receive these 3 sensors, you will be responsible for reporting all glucose values collected by these devices to your Seamar clinical team, and will need to contact your Seamar clinical team if you have problems or questions about using the sensors.

RESPONSIBILITIES

Compañeros en Salud Classes (Both Groups)
It's important for you to complete all the study visits, procedures, and classes to help us learn how helpful the diabetes education program will be.

Blinded CGM: All participants in both groups will wear blinded CGM 10 days before the first diabetes class, after the end of the last class, and again 3 months later.

Compañeros en Salud Classes with RT- CGM
If you are in the Real-Time CGM group, it's important for you to wear the RT-CGM at the scheduled times so that we can learn how helpful the CGM is. We will ask you to wear the CGM for 10 days, for 5 sessions over 12 weeks. If you are unable to wear the CGM, please contact the study staff.

Household member participation:
If you have children ages 8 or older, spouse/significant other, or other household members:

- We will ask if they would also be willing to complete a less than 10-minute questionnaire about their eating habits and activity.
- If you are assigned to the RT-CGM group, we will ask them some questions about CGM (if they are older than 13).

For household members ages 17 or older, if they are not present during your visit, we will ask you if it's OK to call them. If you agree, we will ask them questions by phone or email. We will ask what time is best to reach your household member. NO personal health information will be collected from household members. Name, relationship to you, their age, email and phone number will only be used to contact household members who you think might be interested.

I do not agree to have my household members participate____
I do agree to have my household members participate if they desire____

Advisory board:
A small number of participants may be asked to be on an advisory board. We hope to improve the diabetes classes and discuss any challenges people may be having with participating in the diabetes classes, and challenges with telemedicine sessions. We will ask the first 3 participants who enroll and also the first 2 participants who stop going to the sessions to be on the advisory board. If they choose not to participate, we will continue to ask the next participant enrolled until we have 3 participants who have attended the education sessions and 2

participants who stopped attending the sessions. We will ask you questions either in a group setting or 1:1 tele-visit/zoom or phone interview about living with diabetes and any barriers/difficulties you are experiencing. Interviews will take approximately 45-60 minutes and will audio recorded in order to ensure all answers are understood/collected and then summarized in a general manner about all participants.

RISKS, STRESS, OR DISCOMFORT

ARE THERE RISKS IN THIS STUDY?

Risks related to your normal medical care are not listed in this form. We encourage you to discuss these with your study doctor, your primary care provider, or another health care professional.

Taking part in research involves some risks of physical or psychological injury or discomfort. There is always the possibility of unknown or unexpected injuries that might occur.

The most likely risks of this study are described below:

Continuous Glucose Monitoring
The CGM sensor may cause pain when it is inserted into the skin, like a pump site insertion or insulin shot. Rarely, a skin infection can happen at the site of insertion of the sensor. Itchiness, redness, bleeding, and bruising at the insertion site may happen. An allergy to the tape that holds the sensor to the skin is possible. The risk of skin problems could be greater if you use a sensor for longer than is supposed to be used. There is a chance that the sensor or needle may break under your skin. This is not expected to occur, but if it does, you should ask your study doctor what to do.

Like glucometers, or blood glucose meters, that you may currently use, it's possible that the CGM may fail to give accurate reading. This may happen due to malfunction, battery issues, or accidentally turning off alarms. If you feel different than your CGM blood sugar reading, you should check your blood sugar with the glucose monitor your primary care provider has given you previously for your diabetes monitoring.

Using acetaminophen (Tylenol) can give inaccurate readings if you take more than the recommended dose of 3000 mg daily. We recommend you do not take more than the recommended dose of this medication.

With the CGM device, you may feel uncomfortable or unsure about wearing a medical device on your body for 10 days at a time.

Risk of Hypoglycemia and Hyperglycemia
As a person with diabetes, there is always a risk of having low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia). Symptoms of low blood sugar can include sweating, weakness, shaking, and not feeling well. Symptoms of high blood sugar may include increased thirst, tiredness, blurred vision, and irritability. The diabetes classes will teach you

how to avoid low blood sugar and what to do if this happens. As well, if you see very high sugars, you should go see your primary care doctor to help you manage the high sugars.

Fingerstick Discomfort
When we do a fingerstick for the A1C test, you may have slight discomfort at the puncture site. This is similar to the fingerstick you do when testing your blood sugar. There is also the risk of lightheadedness, bruising, and possible infection with fingersticks for diabetes.

Questionnaires and Clinical Measures
We will ask you questions about your attitudes, feelings and behaviors related to diabetes and in general. Though uncommon, it is possible that some people may find these questions to be a little bit upsetting. You can refuse to answer any questions that make you feel uncomfortable. You can decide not to answer questions, take a break, or stop taking part in the study at any time. Many precautions will be taken to keep your information confidential, but this is not a guarantee.

Diabetes classes will be provided virtually by Zoom, or in person, at a designated Seamar location. Patient Navigators (PA) s and health educators will use Sea Mar education offices/space to lead sessions. Evening sessions may be led from the educator's home using a private space to ensure participant's privacy.

Loss of Privacy
We will collect blood sugar numbers from the CGMs that we will give you. We will have detailed information about your diabetes and daily health habits. Some people may be uncomfortable with this. The study team will see your CGM data. We will also see the information used to create study accounts for CGM data downloads. Because the diabetes classes will take place in a group, others who are attending the classes may see you and hear what questions you ask or information you share.

Blood pressure cuff: The blood pressure cuff may cause slight discomfort when it inflates, but it deflates in seconds.

Advisory board and 1:1 Interviews: You might feel nervous or embarrassed about talking about why you stopped attending the sessions or barriers to health care for diabetes. If you start to experience stress or discomfort you can choose not to answer the questions, take a break or stop the interview all together.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you do not take part in the study, you may continue your current diabetes treatment and blood sugar monitoring. We encourage you to discuss your options with study staff, your primary care physician, or another health care professional who is familiar with type 2 diabetes. There are other education classes available at Sea Mar and other health centers for diabetes management/education. However, currently CGM is not paid for by insurance in patients with type 2 diabetes who take less than 3-4 shots of insulin a day. If you do want to use CGM outside the study, your primary care provider could prescribe it, but you would have

to pay the complete CGM cost out of pocket (each sensor costs $35-70 depending on the type of CGM device you are using).

BENEFITS OF THE STUDY

There may be a possible medical benefit to you if you decide to take part in the study, but it is not a guarantee. You may receive no direct benefit from being in the study. People who take part in this research study will add to new knowledge that may help other people with type 2 diabetes.

CONFIDENTIALITY OF RESEARCH INFORMATION

All the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or University staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

WHAT IF I WANT TO WITHDRAW FROM THE STUDY, OR I AM ASKED TO WITHDRAW FROM THE STUDY?

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You may continue to receive medical care not related to this study. We encourage you to talk to a member of the research group, so they know why you are stopping the study. No penalty or loss of medical care will result from your decision. You may continue to receive medical care not related to this study. We also may ask you to be on the advisory board and or do an exit interview so that we can learn how to improve the program.

If you are pregnant, we will withdraw you from the study and not gather any more data. We would ask that you seek care from your primary care provider.

Returning Results to You

You will receive the results of the laboratory testing (A1c). You will also be able to see your blood sugar in real-time if you are in the RT-CGM group. If you are not in the RT-CGM group, the health care educators at Sea mar will be given your blood sugar numbers at the end of the study and you may be able to review the results with your doctor. If you say in the initial questionnaire you have any thoughts about harming yourself, we will immediately call you and help you to get help.

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ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The study will pay only for testing related to the study. The costs of treatment, office visits and tests for your diabetes and other medical conditions will be your or your insurance company's responsibility. This is considered standard care.

The study will pay for the costs of all research supplies and procedures that you will have specifically for the study. These will include the education materials and the CGM system and sensors, and pedometer if needed. Occasionally you may see increased data usage or quicker loss of battery on your smart phone with the use of the CGM app (Clarity). If this happens, please notify the research team so we can help you with this issue.

Compensation

If you take part in the study, you will receive a $50 gift card for each data collection visit, for a total of $150 if you complete three data collection visits. If additional unscheduled visits are required, you may receive up to an additional $50.

Your household member will also receive a $15 gift card for completing the survey/questionnaires. If you are asked to also be on an advisory board to improve the education program and telemedicine, you and your household member will also be given a $50 gift card for every hour spent on advisory board (likely $100 for each meeting or $200 dollars total). You will receive a $50 gift card for every hour you spend on the 1:1 interviews .

As an extra incentive for attending educational sessions, a $25 gift card will be given for attending 4 educational session or more. An additional $25 gift card will be given for attending 8 educational sessions or more.

Who can I call with questions, complaints or if I'm concerned about my rights as a participant?

If you think you have a medical problem or illness related to this research, contact Dr. Nicole Ehrhardt or another research team member right away at the number(s) provided in this document. She will treat you or refer you for treatment.

If you have any questions about your rights as a research subject or if you have questions, concerns, or complaints about the research or being in this study, you should contact: the UW Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940.

Use of data and specimens

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify

you. If we do, a review board will decide whether or not we need to get additional permission from you.

Source of Funding

This research study is supported by a grant from the American Diabetes Association. In addition, Dexcom (the maker of the CGM being used in the study) has provided CGM supplies at reduced cost to the study team.

Statement of the Subject:

I have read this consent form and the research study has been explained to me. My questions have been answered to my satisfaction. I understand that by signing this form, I have not waived my legal rights nor released anyone from negligence. I chose to volunteer for the study. I have been given a copy of this form.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

Consent Presenter Statement

I have provided this participant with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

_____

Printed name of study staff obtaining consent Date

_____

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject
Subject's Medical Record (if applicable)

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