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Effectiveness of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes: The CUT- DM with CGM for Latinx randomized controlled trial study protocol.

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Abbreviations:

Persons of Latin American cultural or ethnic identity in the United States (Latinx)
Type 2 Diabetes (T2D)
Real-time continuous glucose monitoring (RT-CGM)
Diabetes self-management education and support (DSMES)
Federally Qualified Health Center (FQHC)
Hemoglobin A1C (A1c)
Health Educator (HE)
Community Healthcare Worker (CHW)
Research Electronic Data Capture (REDCap)
Certified Diabetes Educator (CDE)
Young Men's Christian Association (YMCA)

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We acknowledge Dr. Sinclair's lifelong dedication to empowerment and support of vulnerable populations and her initial work on the culturally tailored diabetes education curriculum. We sadly report her passing during her current work on this project.
We thank Tamara Swigert, RN, MSN, CDCES at Children's Hospital Colorado for her initial work on the CGM education materials.
We also thank Darinka Gil Menchaca, Sea Mar and Evelin Jones, University of Washington, for their significant work on the curriculum translation.

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Abstract

Introduction: The prevalence of type 2 diabetes (T2D) is increasing in the Latinx community. Despite telehealth and technology becoming more available, these resources are not reaching the Latinx population. Diabetes education is a cornerstone of treatment; however, access to culturally tailored content is a barrier to the Latinx population. Real-time continuous glucose monitoring (RT-CGM) is a patient-empowering tool that can improve glycemic control, but it is not readily available for Latinx patients with T2D. We aim to evaluate a culturally tailored diabetes self-management education and support (DSMES) curriculum, using a team-based approach to improve glycemic control, promote healthy behaviors and enhance patient access with the use of telehealth in Latinx individuals. The primary aim of the study is to evaluate the additive effectiveness of RT-CGM on glycemia and behavioral changes among Latinx patients undergoing a culturally tailored DSMES. A sub aim of the study is to evaluate family members' change in behaviors.

Methods: We propose a randomized controlled trial of blinded versus RT-CGM with 100 Latinx participants with T2D who will receive DSMES via telemedicine over 12 weeks (n=50 per group). The study will be conducted at a single large Federally Qualified Health Center (FQHC) system. The control group will receive culturally tailored DSMES and blinded CGM. The intervention group will receive DSMES and RT-CGM. The DSMES is conducted by community Health Educators (HE) weekly over 12 weeks in Spanish or English, based on participant's language preference. Patients in the RT-CGM group will have cyclical use with a goal of 50 days wear time. The primary outcomes are changes in A1c and CGM-derived metrics at 3 and 6 months. The secondary outcomes include participants' self-management knowledge and behavior and household members' change in lifestyle.

Ethics and dissemination: The study proposal was approved by the University of Washington ethics/ IRB Committee as minimal risk (IRB ID: STUDY00014396) and the Sea Mar IRB committee.

Trial registration number: ClinicalTrials.gov identifier: NCT05394844

Keywords: Diabetes and Endocrinology, Health Equity, General Medicine

Strengths and Limitations of Study:

⇒ Training in digital literacy is an integral part of the study.

⇒ Culturally tailored DSMES is delivered through a telehealth platform to increase geographic outreach.

⇒ All curriculum and behavior modification surveys are available in both English and Spanish.

⇒ This RCT maybe underpowered if retention is less than expected.

⇒ Behavior modification of participants' household members after DSMES with and without RT-CGM with no direct intervention targeting household members is also evaluated.

Introduction: The prevalence of diabetes in adults in the U.S. now exceeds 14%, with T2D accounting for 90-95% of all cases.[1] Diabetes incurs healthcare costs of over $200 billion annually in the U.S. alone[2] and is the leading cause of blindness, chronic kidney disease, heart disease, and amputations[3]. The Latinx population is disproportionately affected by T2D, with a prevalence that is 80% higher than in non-Latinx whites[4]. Latinx individuals with T2D experience higher rates of diabetes-related complications including retinopathy and chronic kidney disease[5] Latinx individuals with diabetes also face greater challenges accessing medical care and pharmacotherapies[6]. Diabetes Education is an integral part of diabetes self-care and empowerment. However, broader implementation of behavioral interventions has been limited to date by 1) lack of data-driven design, 2) inadequate patient access, and 3) absence of culturally tailored curricula that are essential for reaching specific populations[7,8]. Culturally tailored DSMES curricula are promising, but clinical data on optimal approaches for implementing these programs are limited, with a particular scarcity of data in Latinx populations[9,10].

The DSMES curriculum *Compañeros en Salud* (Partners in Health)[11] is a multi-cultural and bilingual 12-module program that was created specifically for Latinx populations to improve diabetes self-management. *Compañeros en Salud* was first tested in the Latinx population as five 2-hour sessions under the name "*El Camino a la Salud"* and has been evaluated in two previous studies[12-14]. In response to feedback on the initial curriculum, author Sinclair (formerly named Two Feathers) updated the name to *Compañeros en Salud* in order to highlight the "communal" strength in the Latinx population and changed the delivery to twelve 1-hour

sessions in order to increase focus. The 12-session hourly curriculum was first studied in Native Hawaiians and Pacific Islanders[15] and then piloted in an English-speaking Latinx population with in-person sessions in Seattle, WA[16]. DSMES is the foundation of diabetes self-management, but additional tools are needed to reinforce behavioral change and to support participants' self-empowerment. The use of RT-CGM is a highly effective intervention for improving glycemia in patients with type 1 diabetes[17-20], but its use in patients with T2D is limited, in part due to insurance barriers[21,22]. The American Diabetes Association's (ADA) guidelines highlight the utility of CGM for patients using non-insulin or basal insulin regimens[23]. We previously showed that cyclical RT-CGM use over 3 months significantly improved A1c in subjects with T2D not using prandial insulin[24] and that this improvement was sustained beyond the period of RT-CGM use[25]. Other studies using intermittent flash CGM technology and a multi-center CGM intervention in primary care clinics showed similar results[26,27]. A key factor behind these benefits may be behavior modification associated with RT-CGM, however, studies are lacking[28]. Despite these benefits, CGM is not readily available to many people living with T2D[21,22]. A small, single group pilot study with 15 Latinx adults evaluated the *Compañeros en Salud* DSMES curriculum and RT- CGM intervention in Seattle, WA[16]. The average baseline A1c of 9.3% improved to a post-intervention A1c of 8.5% ($p<0.01$). Participants lost an average of five pounds and there were significant improvements in systolic ($p=0.03$) and diastolic ($p=0.002$) blood pressure. Our exploratory data demonstrate both acceptance of and perceived benefit from RT-CGM in Latinx individuals with T2D. Telemedicine[29,30] offers a novel strategy for addressing the lack of access to diabetes education, one of the largest barriers to improving diabetes control and a common challenge for the Latinx population[7,8]. Telemedicine is often underutilized in populations such as those that identify as Latinx[31-33], as digital literacy and access to broadband internet are barriers that contribute to health inequalities in this population.

Beyond the impact of direct interventions on study participants, we are interested in the impact on other individuals in the participants' lives. Spouses and partners of individuals with diabetes are at increased risk for developing T2D[34-35]. Children are more likely to develop obesity if they have family members living with this disease[36] and have a 20-40% absolute risk for developing diabetes if they have a parent with T2D[37]. Diabetes in a family member has been shown to have a higher positive predictive value for developing T2D compared to obesity[38].

This elevated risk, particularly in Latinx communities, is thought to result from a combination of genetic and environmental factors including shared nutritional and physical activity behaviors[39,40]. Interventions that promote behavioral modification in an individual patient may have the potential to impact other members of the household**.** Family-based interventions are effective at reducing childhood obesity[41,42], a meta-analysis concluded that parent-only interventions are as effective as parent-child interventions for mitigating childhood obesity[43]. Studies have also demonstrated an effect on spouses not participating in the intervention[44-47]. This study has an exploratory objective to look at whether this intervention reaches household members in a so called "ripple" effect.

Aims and Objective*s:* The primary aim of this study is to determine the additive effectiveness of RT-CGM among Latinx T2D patients undergoing culturally tailored DSMES curriculum at improving glycemic indices (including A1c and CGM outcomes) at 12 and 24 weeks. The secondary objectives are to evaluate changes in blood pressure, lipid profile, waist circumference, medication adherence, lifestyle and diabetes distress changes and social determinants of health. A sub aim of this study is to explore whether a "ripple effect" on nutritional or activity behaviors is observed in household members.

Study Design

This study is a randomized controlled parallel group trial of DSMES with and without RT-CGM among Latinx patients with a diagnosis of T2D. Intervention assignments were generated (1:1 to either blinded CGM + Education or RT-CGM + Education) using permuted block randomization with block sizes of 2, 4, or 6. Randomization was stratified by baseline A1c (< 9.0 or ≥ 9.0) upon confirmed eligibility and consent using a REDCap database (Research Electronic Data Capture, Vanderbilt University). An independent study statistician generated the randomization lists and is unblinded, though has no direct involvement with patients or outcomes assessors. The RC, HEs, CHW and participants are unblinded to the intervention, but the PI and CO-I's are blinded to participants and their intervention. Outcome measurements are evaluated at baseline and after 12 and 24 weeks (figure 1).

Population*:* Participants in this study are Latinx patients with T2D who receive care from one large, federally funded health care system in the greater Seattle area. Initial review of the 6 main clinics where potential recruitment occurs showed >450 Latinx patients with A1c >8.0%.

Inclusion and Exclusion Criteria: The goal is to recruit those that identify as Latinx with poorly controlled T2D (A1c > 8.0%). See Table 1 for a full list of inclusion and exclusion criteria.

Recruitment: Patients are identified both by review of the most recent A1c documented in the electronic medical record and by screening clinicians' and health educators' (HEs) office visit schedules in search of patients with a diagnosis of T2D. Additionally, flyers distributed in the community at places of worship, Young Men's Christian (YMCA) facilities and other local community areas serve to further enhance community engagement. Participants are asked whether we may contact household members >8 years old to participate in 2-3 short surveys. Recruitment is quarterly and begins 1 month prior to each 12-week educational cycle. A total of 4-6 DSMES cycles are needed to reach 100 active participants, defined as those that complete at least 1 educational session.

Sample Size Estimation*:* We will enroll up to 130 participants to obtain a total of n=100 study participants who complete at least 1 educational session. The study is designed and sized first for assessing the change in A1c from baseline to 12 weeks among all study participants and secondarily to assess the impact of RT-CGM. To assess statistical power, we assume a standard deviation in baseline A1c of 1.2 and a reduced standard deviation of 1.0 at 12 weeks to reflect an anticipated reduction in A1c due to the *Compañeros en Salud* curriculum. We further assume a correlation in A1c measurements of r=0.5, which is likely to be higher, resulting in greater statistical power. Finally, assuming a 15% reduction in the effect sample size (n=85) due to attrition, the study is sized to detect reductions in A1c of 0.4% or larger with 90% statistical power. If the actual correlation between baseline and week 12 A1c measurements is r=0.7 or higher, the study has 90% power to detect differences in A1c as small as 0.3%. Under similar assumptions, the study is sized to detect a 0.6% difference in 12-week A1c between subjects randomized to RT-CGM vs. blinded CGM (power = 0.82 assuming r=0.5; power=0.93 assuming r=0.7). A two-sided type 1 error rate of 0.05 is assumed throughout.

Statistical Analysis: The primary endpoint is the change in A1c from baseline to 12+/-2 weeks (end of the intervention period). Secondary outcomes include between-group differences in change in A1c at 24+/-2 weeks and changes in body weight, BMI, and blood pressure at 12+/-2 and 24+/-2 weeks. We will use simple descriptive statistics to quantify between-group

differences in changes in CGM indices, including time in range (TIR) mean glucose, mean amplitude of glycemic excursions (MAGE), times above and below range (TAR and TBR), and coefficient of variation (COV). The primary outcome of A1c will be assessed using a random-intercept random-slope linear mixed effects regression model that adjusts for an indicator of RT-CGM and time (baseline, visit 2, and visit 3) as fixed effects. To assess the effectiveness of the *Compañeros en Salud* curriculum, inference for Aim 1 will focus on the change in A1c from baseline to 12 weeks for the entire cohort (regardless of RT-CGM status). Main secondary outcome measures will be TIR and mean glucose by CGM. Additional outcomes including body mass index, waist circumference, and systolic/diastolic blood pressure will be assessed similarly using a generalized linear mixed effects model appropriate for each type of outcome measurement. We will conduct a missing data analysis to describe and characterize enrolled participants who do not provide data due to attrition. Linear mixed effects models naturally handle intermittent missing data through maximum likelihood estimation. As described by Molenberghs and Kenward[48], we will use inverse probability weighting in secondary analysis within each longitudinal regression model to inflate the weights of cases that are underrepresented in the analysis due to selective attrition and/or non-participation. We will also conduct sensitivity analyses using 10-fold multiple imputation to assess the robustness of the results when missing data are imputed. The characteristics of non-responders will be summarized in our final report, and we will present the sensitivity of the estimated treatment effect due to alternative missing data methods.

The effect of wearing RT-CGM on CGM indices will be assessed using a similar analytic framework as with the analysis of A1c. The linear mixed model coefficient for RT-CGM will be coded to estimate the average difference in 12-week change in outcomes due to receiving real-time glucose data on the outcome of interest. The effectiveness of the *Compañeros en Salud* curriculum on glycemic outcomes, sugared beverage intake, steps/day, reported walking, and diabetes distress will be assessed both overall and by RT-CGM status, and models will additionally adjust for an indicator of survey language (English vs. Spanish). Finally, exploratory outcomes include changes in nutritional behaviors for household members, specifically sugared beverage intake. Secondary outcomes for household members will include perception of benefit for the household member not actively engaged in the intervention or wearing the CGM. The outcomes of household members will be measured and assessed similarly

but in separate generalized linear mixed effects models. For participants with involved household members, we will examine the associations of behavioral and dietary outcomes between participants and household members through direct adjustment of participant data in household member outcome models. We will explore temporal associations using time-lagged participant outcomes in the longitudinal model.

Data Collection: All data will be collected by HEs or CHWs and stored in REDCap (figure 2). CGM data will be reviewed and inputted by a study research coordinator. The following data will be collected from participants, when appropriate, using validated tools at baseline (Visit 1) and after the intervention period (3 months/Visit 2 and 6 months/Visit 3). Participants will be provided with compensation for each visit completed.

Patient demographics: Age, gender, presence of diabetes complications, co-morbidities, smoking status, alcohol use, medications, cohabitation, educational level, health insurance status, household income, access to internet and smart phone or personal electronic device will be collected directly from the patient.

Anthropometric, vital sign, laboratory, and pedometry measurements: Height will be measured by a stadiometer. Weight will be measured using a Digital scale, and BMI (kg/m^2) will be calculated. Waist circumference will be measured using a flexible measuring tape. Participants will remain in a seated position for a minimum of 15 minutes prior to measurement of resting heart rate and blood pressure with an Omron Professional Digital blood pressure and heart rate monitor. Current A1c will be assessed by DCA Vantage Analyzer at all visits. Participants will be given a pedometer or if preferred will use one available on their smartphone. CGM data will be collected for 10 days after the first visit and for the 10 days prior to each of visits 2 and 3.

Glucose/CGM Data /Evaluation Outcome Measures: For participants in both the education-only and RT-CGM study arms, the % time the CGM device was worn over each period of use will be captured. Glycemic outcome measures include time in range (TIR), mean glucose, coefficient of variation, mean amplitude of glucose excursion (MAGE), % time below range (TBR) (<70 mg/dL), and % time above range (TAR) (>180 mg/dL). Between-group comparisons for CGM-derived glycemic metrics will be assessed based on changes from baseline to study week 12 and baseline to study week 24.

Patient Reported Outcome Measures: Participants will be asked questions about nutrition, physical activity, depression, diabetes distress, self-care, food insecurity and neighborhood safety. See a full description in Table 2.

The Intervention:

The DSMES curriculum: *Compañeros en Salud[11]* entails 12 hour-long weekly educational classes that will be led by CDEs and HEs. The intervention emphasizes ADA clinical goals for blood glucose, A1c, blood pressure and lipids, and is designed to reduce risk factors associated with T2D complications by optimizing T2D self-management activities (Table 3). Target behaviors include healthy eating, physical activity, blood glucose monitoring, medication adherence, problem-solving, healthy coping, communicating with one's healthcare team, asking for support from family and friends, taking an active role in individual healthcare, and understanding what kind of T2D care is needed. The curriculum is written in a conversational tone in plain language that facilitates learning for participants with little formal education and ensures intervention fidelity. Group discussion, role-playing, problem-solving, and hands-on activities are included to encourage engagement and enhance learning. Sociocultural strategies, which present T2D in the context of cultural values and community characteristics, are incorporated to increase the intervention's salience to participants. For example, a facilitator might begin a class with a story about ordinary community members with T2D, using culturally relevant metaphors to link their situation with effective self-management behaviors.

Medical Device: *CGM (DEXCOM (G6))[49]:* A continuous glucose monitor (CGM) is a tool that allows measurements of glucose levels in real-time throughout the day and night. A tiny electrode called a glucose sensor is inserted under the skin by a skin prick to measure glucose levels in tissue fluid for 10 days. The RT-CGM-education intervention group will wear the RT-CGM cyclically. The intervention participants will have RT-CGM data downloaded after 3 cyclic sessions of use and at 5 sessions of use and wear the CGM blinded at baseline and 24 weeks. The Blinded-CGM education group participants will wear the blinded CGM at baseline, at 12 weeks, and 24 weeks. CGM Ancillary Devices Dexcom CLARITY® is an accessory for users of the Dexcom CGM system and it allows the transfer of glucose data from the CGM

system to Dexcom remote servers for data management to allow the use of the CGM data by the user and by study personnel. Additionally, if participants desire, the Dexcom G6 CGM System comes with a built-in Dexcom Share feature allowing up to 10 people to follow a participant's glucose levels, providing a circle of support. By downloading the Dexcom Follow app, followers can view participant's glucose data directly from their smart device. For participants who do not have a smart phone, one will be provided to them.

Education and Evaluation tools in Spanish: *Compañeros en Salud[50]*, CGM Education material and behavior modification questionnaires for CGM are in Spanish. The culturally tailored English educational materials[11] for the Latinx population have been piloted in a small English speaking Latinx population and have been translated to Spanish by the HE, native speaking research personnel and a Latinx physician on the research team who is also a native speaker[50]. A questionnaire for perception on how CGM affects/changes lifestyles[51] was previously developed and is now also available in Spanish (Supplementary Material 1). Finally, a RT-CGM educational handout to explain glucose goals and how food and activity affects blood sugar was developed by an endocrinologist team-member and diabetes educational specialist and is available in both English and Spanish (Supplementary Material 2 and 3).

The DSMES curriculum with and without RT-CGM is an adjunct to participants' current diabetes management in their primary care clinic which continues throughout the intervention and encourages engagement with their healthcare provider.

Patient /Public Involvement*:* The initial protocol was modelled after a telemedicine Diabetes Prevention Program completed by our community partner FQHC during the COVID-19 pandemic. We have completed the first cycle of the education intervention and 15% of first pilot cycle participants (including those who completed at least 50% of the education curriculum plus those who dropped out of the program) completed detailed interviewing with topics including: perceptions of the educational program, comfort using telemedicine, barriers to taking care of health/diabetes and participation/engagement in the intervention, and suggestions to increase enrollment and to improve cultural tailoring. These interviews will be repeated in cycle two to further adapt/improve the program. The Washington State Department of Health, the Washington State Health Authority and local Latinx community advocacy programs have been

engaged early to support the program and to begin discussions about sustainability and replication.

Digital Literacy: HE or CWH will engage participants no more than 4 weeks prior to the start of the DSMES intervention to ensure participants have a working technology platform for the education sessions and to provide smart phones with data plans if needed. For all participants, CHWs/HEs will teach simple CGM insertion (blinded and RT). For those who are enrolled in the RT-CGM arm, the CHWs/HEs will set up a mobile app for the RT-CGM device. HEs/CHWs will conduct a single 30-minute training session on CGM for participants in the study, with particular focus on the use of RT-CGM as a tool to understand the impact of food and activity choices. The DMSES curriculum *Compañeros en Salud* will be led by the HEs weekly and will take place on a digital platform and are encouraged but in person sessions are available. Sessions are recorded but live attendance is strongly encouraged.

Ethics and Dissemination: The study proposal was approved by the University of Washington ethics/ IRB Committee (IRB ID: STUDY00014396 date 1/7/2022) and the Sea Mar IRB committee and funded by the American Diabetes Association Disparities of Health Care grant 11-21-ICTSHD-51. The findings will be published in peer-reviewed journals and presented at scientific conferences. All recruited patients will be informed by the HE/CHW, verbally and in writing, about the objectives, methodology, tests, and interventions they receive if they participate in the study. Patients will be included if they grant permission and sign the informed consent. Household members will give verbal assent. The consent document is available in both Spanish and English (Supplementary Materials 4 and 5). All participant information will be stored on REDCap. Any modifications to the protocol will require a formal amendment to the protocol and acceptance by the ethics committee. We plan to publish the findings in peer-reviewed journals and share our findings at scientific conferences. The investigators will consider authorship following widely accepted criteria.

Limitations of the Study:

This study is limited due to involving only a single center and smaller sample size. All participants receive an intervention with DSMES to enhance diabetes knowledge. We believe

that those that receive RT-CGM with DSMES may have better initial diabetes indices after the DSMES intervention is completed given real-time feedback from CGM, and sustained improvement at 6 months without further intervention. However, the study may be underpowered if retention is less than expected. We will aim to recruit up to 130 participants given a likely 20-30% drop out prior to education given the population served. This estimate is based on experience by the community partner with other diabetes education programs. We additionally do not have funding to evaluate longer-term effects (>1 year). While there may be initial improvement after intervention at 3 months and 6 months, long-term follow-up will need to be explored in future studies. Finally, although culturally tailored interventions are important, due to the heterogeneity within the Latinx population, adapting a single educational curriculum to reach all Latinx participants from many different backgrounds remains a challenge. We intentionally elected to use HE's and a bilingual bicultural physician working in the local community as the primary translators of the curriculum, with the purpose of capturing cultural nuances that may benefit communication with the participants. A formal translation service was not utilized, and we recognize that this could also be a potential limitation.

Table 1: Inclusion and Exclusion Criteria

Inclusion criteria:	**Exclusion Criteria:**
Participants must be 18 to 60 years old	Duration of diabetes > 15 years
Self-identify as Latinx.	Type 1 diabetes or latent autoimmune diabetes
A clinical diagnosis of T2D within the last 15 years with or without medication use	Current use of prandial insulin
A1C ≥8.0% at screening	Any condition that prevents walking at least 1 city block
Be physically and cognitively able to use the home CGM monitoring device	History of serious mental illness other than adequately treated depression
Be willing and able to follow all study procedures	History of bariatric surgery or current participation in a weight management program
	Current diagnosis of cancer or other serious or systemic medical condition or significant active cardio- or cerebrovascular disease after review by PI
	Pregnancy

	Known history of hypoglycemia unawareness

Table 2: Weekly Education Session Topics for *Compañeros en Salud.*

Session	Topic
1	Glucose Balance
2	Diabetes Medication
3	Food
4	Diabetes Diets
5	Exercise
6	Heart
7	Cholesterol
8	Feet
9	Stress
10	Preventing Complications
11	Diabetes Team
12	Living Well with Diabetes

Table 3: Patient questionnaires about nutrition, physical activity, social determinants of health and perception of benefit of RT-CGM

Nutrition	1. Starting the Conversation (STC) is an eight-item, simplified food frequency instrument[52] 2. 2. The National Center for Health Statistics[53] Six-item short form of the Food Security Survey
Physical Activity and Neighborhood Safety	1. The International Physical Activity Questionnaire (short) is a validated questionnaire that reviews the last 7 days of activity[54] 2. The *Neighborhood Questionnaire/Neighborhood Safety[55] is a* 16-item tool to assess sociability and an individual's satisfaction with the family's neighborhood. It has three subscales, and we will ask the Neighborhood Safety Subscale (items 1, 6, 10, 11, and 12) as a brief assessment of participants' ability to safely engage in physical activity in their neighborhoods 3. International Physical Activity Prevalence Study SELF-ADMINISTERED ENVIRONMENTAL MODULE(PANES)*:[56]* (Questions 2,4,6,9,13,14 and 16 of PANES with be assessed)

Behavioral Health	1. Depression symptoms will be assessed with the Patient Health Questionnaire 9 (PHQ-9)[57] 2. Diabetes distress will be assessed with The Problem Areas in Diabetes Scale 5 (PAID-5)[58] 3. Self-care and Self-efficacy activities will be assessed with the Summary of Diabetes Self-Care Activities (SDSCA0[59] 4. Self-Efficacy for Diabetes scale[60]
RT-CGM	1. Modified Harvard Joslin Diabetes Center CGM experiences, opinions, and expectations[61] 2. Perception of behavior change in nutrition and physical activity from RT-CGM use[51]
Family Member	1. Less than 13 years old habits questionnaire[62] 2. Greater than 13 years old starting the conversation and physical activity questionnaire. 3. Greater than 13 years old perception of CGM use by the family member and behavioral changes made as a result of the family member using CGM

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Competing Interests: Dr. Ehrhardt has been on an advisory board for Dexcom, Bayer and Novo Nordisk and received investigator-initiated grants from Dexcom and educational grants from Merck and Novo Nordisk. Drs. Montour, Wright, Sinclair and Berberian, Bryan Comstock, Brian Cedeno and Gary Ferguson have nothing to disclose.

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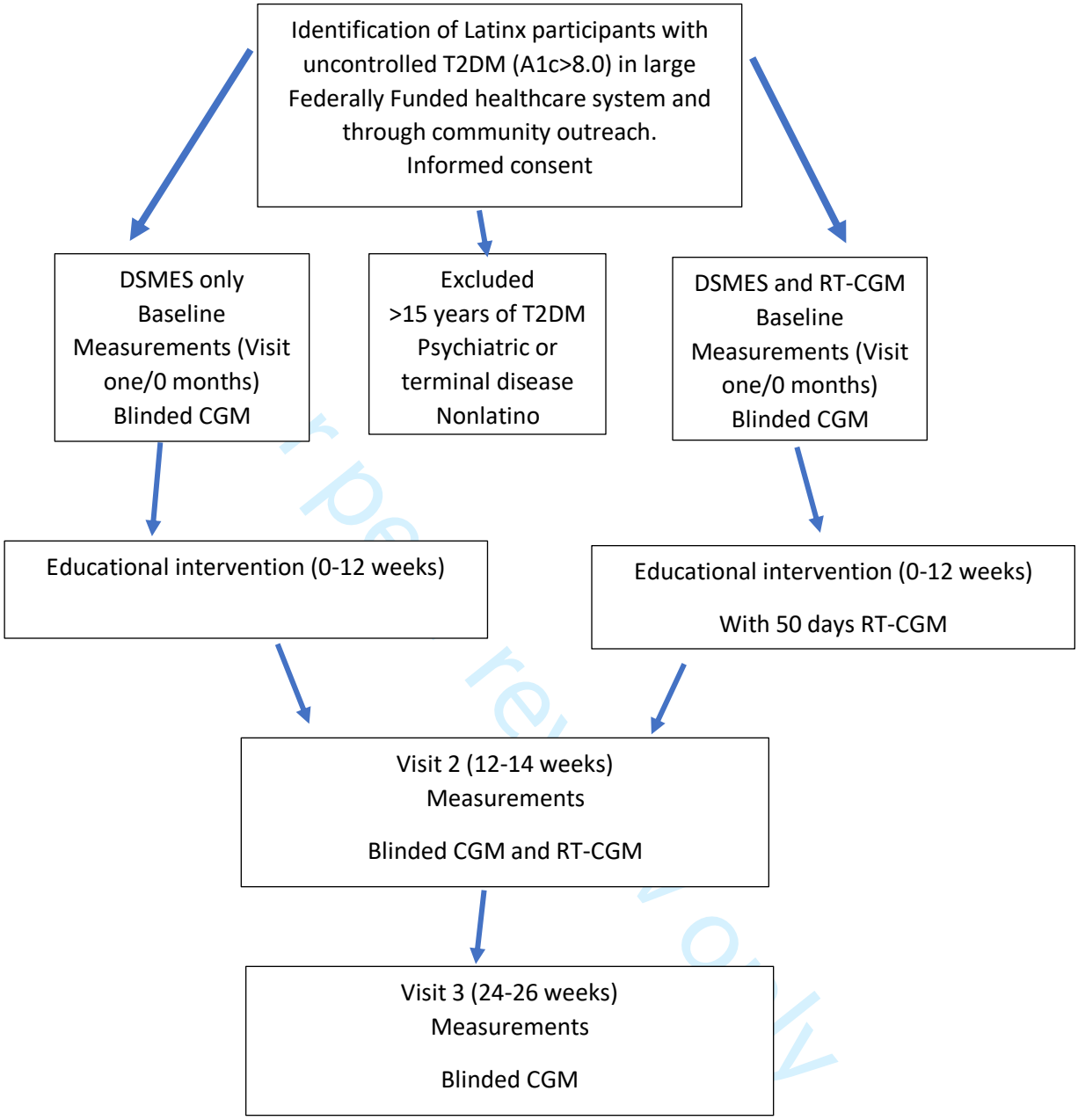
Figure Legend:
Figure 1- Flow chart
Figure 2- Data Collection Schematic


Identification of Latinx participants with uncontrolled T2DM (A1c>8.0) in large Federally Funded healthcare system and through community outreach.
Informed consent
DSMES only
Baseline Measurements (Visit one/0 months)
Blinded CGM
Excluded
>15 years of T2DM
Psychiatric or terminal disease
Nonlatino
DSMES and RT-CGM
Baseline Measurements (Visit one/0 months)
Blinded CGM
Educational intervention (0-12 weeks)
Educational intervention (0-12 weeks)
With 50 days RT-CGM
Visit 2 (12-14 weeks)
Measurements
Blinded CGM and RT-CGM
Visit 3 (24-26 weeks)
Measurements
Blinded CGM

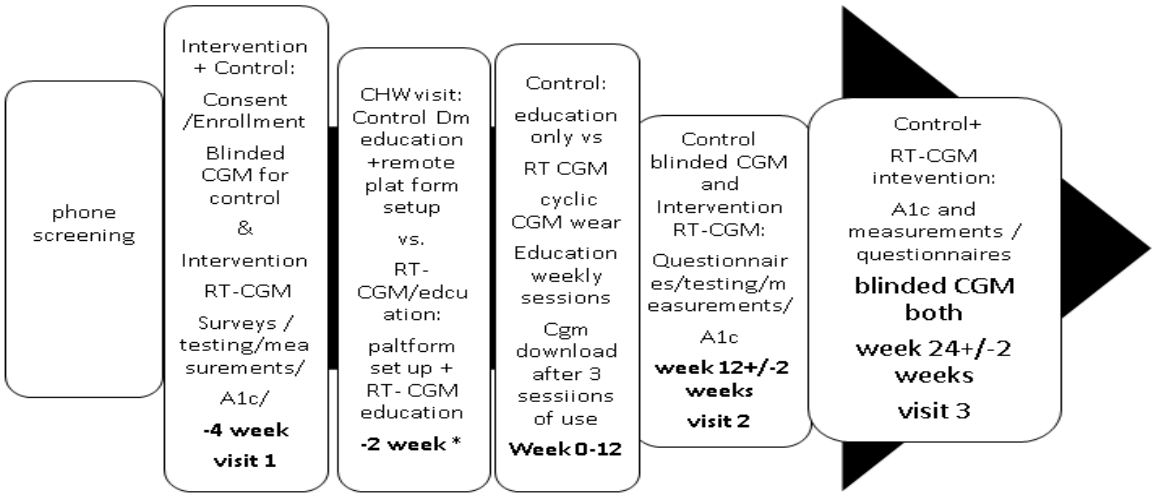


Figure 2: Schematic of Data Collection

IDENTIFICACIÓN: _____ Visita: _____ Fecha: _____

Cambios en el estilo de vida con el monitoreo continuo de glucosa (MCG) Diabetes

Para cada pregunta, marque la opción que mejor describa su experiencia con el Monitoreo Continuo de Glucosa (MCG).

1.Después de la monitorización continua de glucosa
Sientes que:

_ limitaste bebidas azucaradas
_ excluiste bebidas azucaradas
_ no hiciste cambios con respecto a bebidas azucaradas
_ nunca bebiste bebidas azucaradas antes del uso del MCG

2. Después del uso del Monitoreo Continuo de Glucosa:
Sientes que:

_ limitaste el arroz blanco
_ excluiste el arroz blanco
_ no hiciste cambios con el arroz blanco
_ nunca comiste arroz blanco antes del uso del MCG

3. Después del uso del Monitoreo Continuo de Glucosa:
Sientes que:

_ limitaste los cereales
_ excluiste los cereales
_ no hiciste cambios con los cereales
_ nunca comiste cereales antes del uso de MCG

4. Después del uso de Monitoreo Continuo de Glucosa:
Sientes que lees las etiquetas para el contenido de fibra:

_ si
_ no
_ leía las etiquetas para fibra antes del uso del MCG

5. ¿Hay algún alimento que limitó o excluyó después del uso continuo del monitor de glucosa? Enumere los tres principales o diga "ninguno".

_____

_____

_____

_____

6. ¿Piensa que el uso del Monitor Continuo de Glucosa lo hizo más propenso a ser más activo/a aumentar su ejercicio?

__ Si
__ No
__ Ya era muy activo/a
__ No se

7. ¿Era más probable que saliera a caminar o hiciera actividad física después de una comida si observaba un aumento de azúcar en la sangre en su Monitor Continuo de Glucosa?

__ Si
__ No
__ Ya salía a caminar o era activo después de las comidas
__No se

8- Piensa que está tomando su medicina mas regularmente como resultado de su participación en nuestras sesiones educacionales?

__Si

__No

__No lo sé

9. En general, ¿piensa que el Monitoreo Continuo de Glucosa contribuyó a cambios para lograr un estilo de vida "más saludable"?

__ Si
__ No
__ No Se

10. ¿Algo más que quieras contarnos sobre tu experiencia con el Monitoreo Continuo de Glucosa?

Monitoreo continuo de glucosa en tiempo real (RT-CGM) para diabetes

Paquete para participantes

¡Tome el control de su salud!

1. Dispositivo CGM de Dexcom:

El dispositivo de monitoreo continuo de glucosa (CGM) de Dexcom se inserta en la piel a nivel del estómago. Usted puede continuar con todas sus actividades diarias, incluso bañarse y nadar, mientras lo usa.

2. Comida:

En el registro proporcionado, registre cada comida y colación que coma, incluyendo la cantidad. Por ejemplo, si come pasta, registre “2 tazas de pasta” en lugar de solo “pasta”, o si comió queso, registre “3 oz de queso” en lugar de simplemente “queso”.

3- Actividad Física:

Registre la actividad física en el registro proporcionado. Por ejemplo, si va a caminar, registre: “20 minutos caminando a paso ligero” o si sube las escaleras, registre: “subí 3 pisos de escaleras”.

Monitoree su salud usando un CGM en Tiempo Real.

1.Si lo desea, continúe registrando cada comida y colación que come, incluyendo la cantidad.

2. Registre la actividad física.

3. Registre su nivel de glucosa antes de cada comida y, 1 y 2 horas después de cada comida o colación (observe el MGC para su nivel de glucosa en sangre en tiempo real).

Objetivos de glucosa en sangre
Glucosa antes de las comidas: 80 to 110 mg/dL 1 hora después de comer: menos de 160 mg/dL 2 horas después de comer: menos de 140 mg/dL

American Association of Clinical Endocrinologists, 2018

NO se desanime si sus valores son más altos al principio. Piense en lo que puede estar causando esos valores más altos. ¡Haz cambios para ver si puedes bajar esos números!

¡Con el sistema Dexcom RT-CGM podrá ver sus valores de glucosa en tiempo real!

Uso del sistema de monitorización continua de glucosa (CGM) de Dexcom:

1- Usted recibirá lecturas en la aplicación Dexcom G6 en su teléfono inteligente o en el receptor de Dexcom. Dexcom actualiza la lectura de glucosa cada cinco minutos.

2- Si la lectura en su dispositivo no coincide con cómo se siente, debe verificar su glucosa con su medidor.

3- Junto con el valor actual de su glucosa, Dexcom mostrará flechas de tendencia. Las flechas le indican si su nivel de glucosa es estable, si se dirige hacia arriba o hacia abajo y con qué rapidez.

¿Qué significan las flechas?	
	 La glucosa es estable. No cambia más de 1 mg/dL por minuto.
 La glucosa está cayendo lentamente. La glucosa podría disminuir de 30 a 60 mg/dL en los próximos 30 minutos.	 Glucosa está subiendo lentamente. La glucosa podría aumentar de 30 a 60 mg/dL en los próximos 30 minutos.
 La Glucosa está cayendo moderadamente La glucosa podría disminuir de 60 a 90 mg/dL en los próximos 30 minutos.	 Glucosa está subiendo moderadamente. La glucosa podría aumentar de 60 a 90 mg/dL en los próximos 30 minutos.
 La glucosa está cayendo rápidamente. La glucosa podría disminuir más de 90 mg/dL en los próximos 30 minutos.	 Glucosa está subiendo rápidamente. La glucosa podría aumentar más de 90 mg/dL en los próximos 30 minutos.

¿Qué cosas afectan la glucosa?

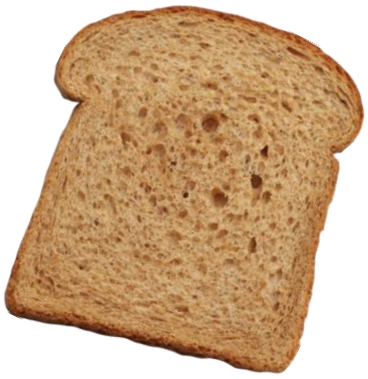
Muchas cosas pueden hacer que su nivel de glucosa suba o baje. Los alimentos pueden afectar su glucosa. Ciertos tipos de alimentos pueden elevar su nivel de glucosa más rápido y alto que otros.

Effect of FOOD on Glucose
↑ Carbohidratos
↑ Grasa
→ Proteína
↓ ↑ Alcohol

→ ningún efecto sobre la glucosa
↑ eleva la glucosa
↓ reduce la glucosa

Carbohidratos

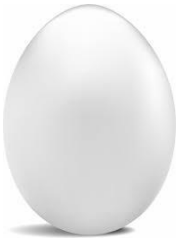
1. Los carbohidratos incluyen azúcares y almidones. Los azúcares se encuentran en alimentos como postres, frutas y algunos lácteos. Los almidones incluyen alimentos elaborados con granos (pan, cereal, arroz, etc.) y algunas verduras con almidón como guisantes, papas y frijoles. Los carbohidratos pueden incluirse en una dieta saludable. ¡Pero la CALIDAD y la CANTIDAD son importantes!



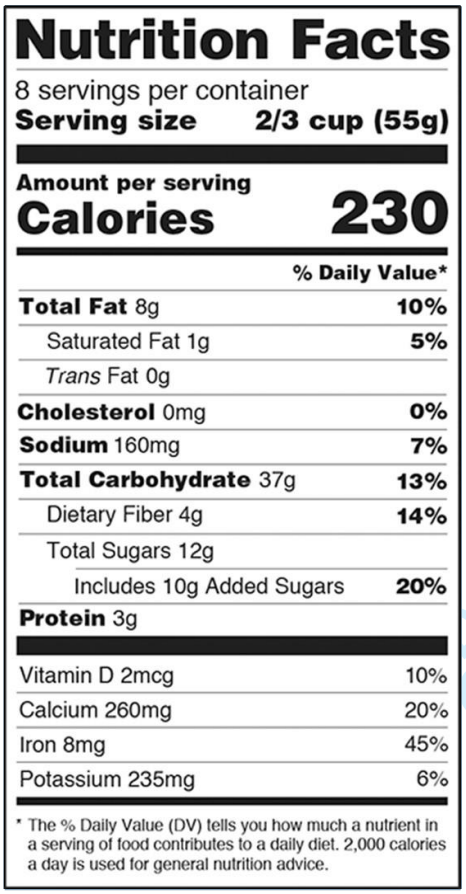
2. Los carbohidratos con fibra tienden a ser de mejor calidad que los que no tienen fibra. Revise las etiquetas de sus alimentos cuando elija sus carbohidratos y trate de comer alimentos con al menos 3 gramos de fibra por porción.

3. Observe su nivel de glucosa después de comer diferentes carbohidratos. Alrededor de dos horas después de una comida, observe que sucede con su glucosa. Por ejemplo, si come 1 taza de arroz y su glucosa sube mucho, considere disminuir a ½ taza o saltearse el arroz por completo. Tenga en cuenta la diferencia en su glucosa.

4. Trate de sustituir diferentes carbohidratos. Toma una tostada integral con 3 gramos de fibra, un vaso de leche descremada y un huevo duro (250-300 calorías). Compare su glucosa con los días cuando come un tazón de cereal y leche (250-300 calorías). Fíjate lo que hace que te sientas satisfecho por más tiempo.



Clave: Límite el tamaño de las porciones y elija alimentos con alto contenido de fibra.



Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Apunta a por lo menos 3 gramos de fibra. por ración y no más de 5 gramos de azúcar agregado.

Azúcar Agregado y Azúcar Natural

1- Como norma, evite los alimentos que tengan más de 5-10 gramos de azúcar agregado. Por ejemplo, el yogur saborizado puede tener entre 18 y 20 gramos de azúcar. Controle su glucosa después de comer su típico yogur en comparación con ½ taza de yogur griego natural con ¼ de taza de arándanos frescos u otra fruta fresca.

2- La fruta es saludable, pero contiene azúcar natural. Demasiada cantidad puede hacer que su glucosa se dispare. Una porción típica de fruta suele ser del tamaño de una pelota de tenis. Los ejemplos incluyen: 1 manzana pequeña, ½ plátano, 3/4 taza de bayas o 15 uvas. Observe su nivel de glucosa después de comer ½ taza de puré de manzana en comparación con una manzana pequeña.

Bebidas azucaradas:

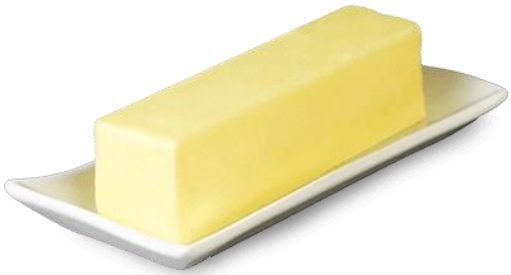
1. Nuestro cuerpo solo necesita agua, pero hemos entrenado nuestros cuerpos para anhelar el azúcar. Los jugos de frutas, las gaseosas, Gatorade®, las bebidas de café endulzadas están llenas de azúcar. ¡Si usted bebe estos, notará un aumento en su valor de glucosa en el RT-MGC!

2. Renunciar a las bebidas azucaradas puede ser un hábito difícil de cumplir, pero marcará una gran diferencia. Trate de sustituir las bebidas azucaradas con agua con limón u otros sabores sin calorías. Note la diferencia en su glucosa. Si sus bebidas son sin azúcar... ¡buen trabajo!

Clave: Evite los azúcares agregados y coma azúcar natural (como en la fruta) con moderación.

Grasa:

1. Gramo por gramo, la grasa contiene más calorías que otros nutrientes. Las grasas pueden estar “ocultas” en los alimentos que ya comemos. Por ejemplo, cuando usted bebe una taza de leche descremada en comparación con una taza de leche al 2%, usted bebe la misma cantidad, pero las calorías en la leche al 2% son bastante más altas. Una taza de porotos verdes con ajo y pimienta en comparación con mantequilla te da la misma cantidad de porotos verdes,



pero muchas más calorías cuando se agrega mantequilla. Eliminar un poco de grasa es una buena manera de reducir las calorías.

2. Si bien no hay "carbohidratos" en las grasas, comer demasiadas grasas puede provocar un aumento sostenido de la glucosa durante muchas horas. Esto se debe a que la grasa causa resistencia a la insulina (la propia insulina de su cuerpo no funciona tan bien). Observe su glucosa de 4 a 8 horas después de una comida rica en grasas. Considere elegir cortes de carne más magros y limitar algunos alimentos ricos en grasas, como la crema agria o la mayonesa.

3. Incluso las “grasas buenas”, como las nueces, pueden aumentar su glucosa, lo que resalta la necesidad de porciones pequeñas, como no más de 15 a 18 nueces por porción. Las grasas no saturadas son mejor opción que las saturadas, pero aún debe prestar atención a la cantidad.

Clave: Recuerde que la grasa es la más alta en calorías. Disminuya sus calorías totales eliminando algunas grasas o cambiando a opciones bajas en grasas.

Alcohol:

Lamentablemente, el alcohol es otra “caloría vacía”. Controle sus niveles de azúcar en la sangre después de una bebida mezclada o una cerveza. Limite el alcohol tanto como sea posible.

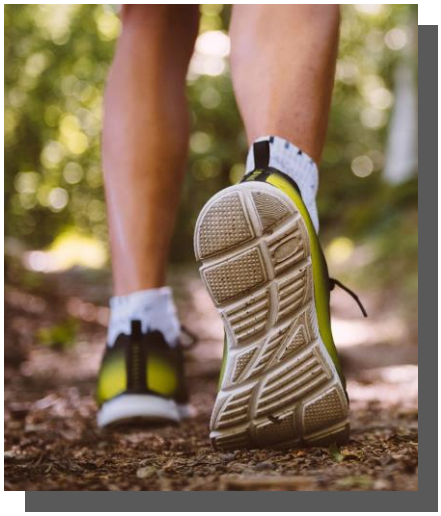
Clave: ¡No beba sus calorías!

Actividad física:

Efecto de la ACTIVIDAD sobre la Glucosa	
→ ↓	Ejercicio de baja intensidad
↑ ↓	Ejercicio de intensidad moderada
↑ ↓	Ejercicio de alta intensidad

1. La actividad física tiene muchos beneficios, incluyendo la pérdida de peso, la reducción de la presión arterial y la mejora del colesterol. Además, la actividad de ligera a moderada, como caminar, puede reducir la glucosa. Apunta a tus 30 minutos al día de actividad de intensidad moderada y luego aumenta con el tiempo. Intensidad moderada significa que su corazón está latiendo un poco más rápido y está respirando un poco más fuerte (sin estar con tanta falta de aire).

2. Considere agregar 10 minutos de caminar o subir las escaleras después de cada comida además de su ejercicio planificado. Utilice su consumo de alimentos como un disparador; después de cada comida, salga a caminar y vea cómo afecta su glucosa.



3. La actividad de moderada a intensa, como el levantamiento de pesas, el entrenamiento en intervalos o las carreras de velocidad, puede aumentar inicialmente el nivel de azúcar en la sangre, pero luego mejorar el nivel de azúcar en la sangre a lo largo del día.

4. Agregue más caminatas a sus actividades diarias. Camine como parte de su viaje. Elija un lugar más alejado en el estacionamiento. En lugar de tomar el transbordador, camine. Vaya por las escaleras. ¡Agregar pasos a su rutina diaria es una excelente manera de aumentar la actividad física y aliviar el estrés!

5. Esté preparado para enfrentar los obstáculos ¿Qué harás si hay mal tiempo? ¿Qué harás si se vuelve aburrido? Si tiene un plan para abordar estas situaciones, es más probable que se mantenga encaminado.
6. Compare su nivel de glucosa en los días en que es más activo frente a los días en que es menos activo.

Clave: La actividad física puede reducir la glucosa, entre otras cosas. Trabajar más "pasos" en su día es una excelente manera de aumentar su nivel de actividad física y todos los beneficios que conlleva.

Glucosa Sanguínea Baja:

1- Si usa insulina o una pastilla que hace que su cuerpo libere más insulina, puede correr el riesgo de tener un nivel bajo de glucosa sanguínea. Cuando pierde peso o elige alimentos más saludables, es posible que necesite menos medicamento(s) para la diabetes.

2- Los síntomas de glucosa baja incluyen temblores, sudar, confusión, sensación de debilidad y posiblemente hambre. Si siente estos u otros síntomas inusuales, verifique con una prueba de punción del dedo en su medidor de glucosa.

3- Para tratar la glucosa baja, debe comer/beber algo con aproximadamente 15 gramos de carbohidratos/azúcar. Esto podría incluir ½ taza de jugo, una taza de lecha descremada, o 3 a 4 tabletas de glucosa. Tomará al menos 15 minutos para que estos azucares tengan efecto. Si su glucosa sigue siendo inferior a 70 mg/dL después de 15 minutos, trate con otros 15 gramos de azúcar.

4- Si tiene lecturas inferiores a 70 mg/dL, debe hablar con su médico. Pregunte si debe reducir las dosis de sus medicamento(s) para evitar niveles bajos de glucosa.

MCG en tiempo real (RT-CGM) Dexcom

Sus metas para los 3 meses: ¡Mejore sus niveles de glucosa y aprenda qué le hacen a su glucosa los alimentos y la actividad!

1. Revise los siguientes valores en su aplicación Clarity para cada sesión de 10 días:

- Promedio de glucosa antes de las comidas
- Promedio de glucosa después de las comidas
- Glucosa promedio durante el período total de uso

2. Identificar los factores que resultaron en los mejores y peores valores de glucosa.

3. Elija alimentos y actividades que mejoren su nivel de glucosa antes y después de las comidas. Continúe registrando su comida, actividad, los valores de glucosa antes y después de las comidas en el registro.

¡Estar saludable o en forma no es una tendencia o una moda pasajera, es un estilo de vida!

The people depicted are not patients and were taken with the participants knowledge.

Real-Time Continuous Glucose Monitoring (RT-CGM) for Diabetes

Participant Packet

Take Charge of Your Health!

1. CGM Device:

The Continuous Glucose Monitoring (CGM) device is inserted in the skin of your stomach, arm or upper buttock. You can continue all your daily activities, including showering and swimming, while you wear it.

2. Food:

In the log provided, record each meal and snack you eat, including the amount. For example if you eat pasta record “2 cups of pasta” rather than just “pasta” or if you have cheese record “3 oz of cheese” rather than just “cheese”.

3. Physical Activity:

Record physical activity in the log. For example if you go for a walk, record “20 minutes brisk walking” or if you take the stairs, log: “climbed 3 flights of stairs”.

Monitor your Health Using CGM Real-Time (RT-CGM)

1. Continue to record each meal and snack you eat, including the amount.

2. Record physical activity.

3. Record your glucose before each meal and 1 and 2 hours after each meal or snack (look at CGM for your real time blood glucose).

Blood Glucose Goals
Pre-meal glucose: 80 to 110 mg/dL
1 hour after eating: less than 160 mg/dL
2 hours after eating: less than 140 mg/dL

American Association of Clinical Endocrinologists, 2018

DON'T get discouraged if your values are higher at first. Think about what may be causing those higher values. Make changes to see if you can get those numbers down!

With RT-CGM you will be able to see your glucose values in real time with the Dexcom system!

Using the Dexcom Continuous Glucose Monitoring (CGM) system:

1. You will receive readings on the Dexcom G6 app on your Smartphone or the Dexcom receiver. The Dexcom updates the glucose reading every five minutes.

2. If the reading on your device does not match how you feel, you should check your glucose with your meter.

3. Along with the current value of your glucose, the Dexcom will show trend arrows. Arrows tell you if your glucose is stable, heading up, or down and how quickly.

What do the arrows mean?	
	Glucose is stable. It is not changing more than 1 mg/dL per minute.
Glucose falling slowly. Glucose could decrease 30 to 60 mg/dL in the next 30 minutes.	Glucose rising slowly. Glucose could increase 30 to 60 mg/dL in the next 30 minutes.
Glucose falling moderately. Glucose could decrease 60 to 90 mg/dL in the next 30 minutes.	Glucose rising moderately. Glucose could increase 60 to 90 mg/dL in the next 30 minutes.
Glucose falling quickly. Glucose could decrease more than 90 mg/dL in the next 30 minutes.	Glucose rising quickly. Glucose could increase more than 90 mg/dL in the next 30 minutes.

What Things Affect Glucose?

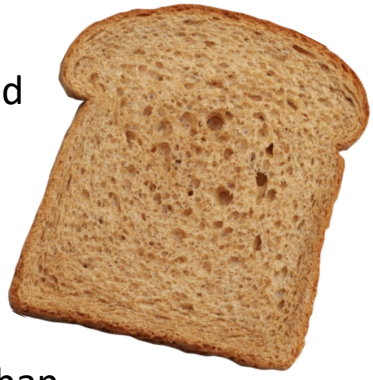
Effect of FOOD on Glucose	
↑	Carbohydrates
↑	Fat
→	Protein
↓ ↑	Alcohol

→ no effect on glucose
↑ raises glucose
↓ lowers glucose

Many things can make your glucose go up or down. Food can affect your glucose. Certain types of food may raise your glucose faster and higher than others.

Carbohydrates

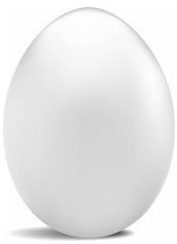
1. Carbohydrates include sugars and starches. Sugars are found in foods such as desserts, fruit and some dairy. Starches include foods made from grains (bread, cereal, rice, etc.) and some starchy vegetables like peas, potatoes, and beans. Carbohydrates may be included in a healthy diet. But QUALITY and QUANTITY are important!



2. Carbohydrates with fiber tend to be better quality than those without fiber. Check your food labels when you are choosing your carbs and aim to eat foods with at least 3 grams of fiber per serving.

3. Notice your glucose level after eating different carbohydrates. About two hours after a meal, notice what happens to your glucose. For example if you have 1 cup of rice, and your glucose goes up a lot, consider decreasing to ½ cup or skipping rice altogether. Note the difference in your glucose.

4. Try substituting different carbohydrates. Have a piece of whole wheat toast with 3 grams of fiber, a glass of skim milk, and one hard-boiled egg (250-300 calories). Compare your glucose to when you eat a bowl of cereal and milk (250-300 calories). Observe what keeps you feeling full longer.



Key: Limit portion sizes and choose foods with high fiber.

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Aim for <u>at least</u> 3 grams of fiber per serving and <u>no more than</u> 5 grams of added sugar.

Added Sugar and Natural Sugar:

1. As a rule, avoid foods that have more than 5-10 grams of *added* sugar.

   For example, flavored yogurt may have as much as 18-20 grams of sugar. Watch your glucose after eating your typical yogurt vs. ½ cup plain Greek yogurt with ¼ cup fresh blueberries or other fresh fruit.

2. Fruit is healthy but is still has natural sugar in it. Too much can cause your glucose to spike. A serving of fruit is typically about the size of a tennis ball. Examples include: 1 small apple, ½ of a banana, 3/4 cup of berries or about 15 grapes. Observe your glucose after eating ½ cup applesauce vs. a small apple.

Sugared Beverages:

1. Our body only needs water but we have trained our bodies to crave this sugar. Fruit juice, sodas, Gatorade®, sweetened coffee drinks all are filled with sugar. If you drink these you will notice a spike in your glucose value on the RT-CGM!

2. Giving up sugary drinks can be a hard habit to break but will make a huge difference. Try to substitute water with lemon or other non-calorie flavors for these sugared beverages. Notice the difference in your glucose. If your beverages are already sugar free… great job!

Key: Avoid added sugars and eat natural sugar (like in fruit) in moderation.

Fat:

1. Gram for gram, fat contains more calories than other nutrients. Fats may be "hidden" in foods we already eat. For example, when your drink a cup of skim milk vs. a cup of 2% milk, you drink the same amount, but calories in the 2% milk are quite a bit higher. One cup of green beans with garlic pepper, versus butter gives you the same amount of green beans, but a lot more calories when butter is added. Cutting out some fat is a good way to reduce calories.
2. While there are no "carbohydrates" in fat, eating too much fat may cause a sustained rise in glucose over many hours. This is because fat causes *insulin resistance* (your body's own insulin does not work as well). Observe your glucose 4 to 8 hours after a high-fat meal. Consider choosing leaner cuts of meat, and limiting some high-fat foods such as sour cream or mayonnaise.

3. Even "good fats" such as nuts can increase your glucose which highlights the need for small portion sizes such as no more than 15-18 nuts per serving/sitting. Unsaturated fats are a better choice than saturated, but you still need to pay attention to the quantity.

Key: Remember that fat is highest in calories. Decrease your total calories by cutting out some fats or switching to lower-fat options.

Alcohol:

Unfortunately alcohol is another "empty calorie". Watch your blood sugars after a mixed drink or beer. Limit alcohol as much as possible.

Key: Don't drink your calories!

Physical Activity:

Effect of ACTIVITY on Glucose	
→ ↓	Light-intensity exercise
↑ ↓	Moderate-intensity exercise
↑ ↓	High-intensity exercise

1. Physical activity has many benefits, including weight loss, lowering blood pressure, and improving cholesterol. In addition, light to moderate activity such as walking can lower glucose. Aim for your 30 minutes a day of moderate-intensity activity and then increase over time. Moderate intensity means your heart is beating a little faster and you are breathing a little harder (without being too out of breath).

2. Consider adding 10 minutes of walking or taking the stairs after each meal in addition to your planned exercise. Use your food intake as a trigger; after each meal, go for a walk and see how it affects your glucose.

3. Moderate to intense activity such as weight lifting, interval training or sprinting may initially increase your blood sugar but then improve your blood sugar over the course of the day.

4. Add more walking into your daily activities. Walk as part of your commute. Choose a farther spot in the parking lot. Walk instead of taking the shuttle. Take the stairs. Adding steps to your daily routine is a great way to increase physical activity and relieve stress!

5. Be prepared to address the barriers. What will you do if the weather is bad? What will you do if it gets boring? If you have a plan to address these situations, you are more likely to stay on track.

6. Compare your glucose level on days you are more active vs. days you are less active.

Key: Physical activity can lower glucose, among other things. Working more "steps" into your day is a great way to increase your physical activity level and all the benefits that go with it.

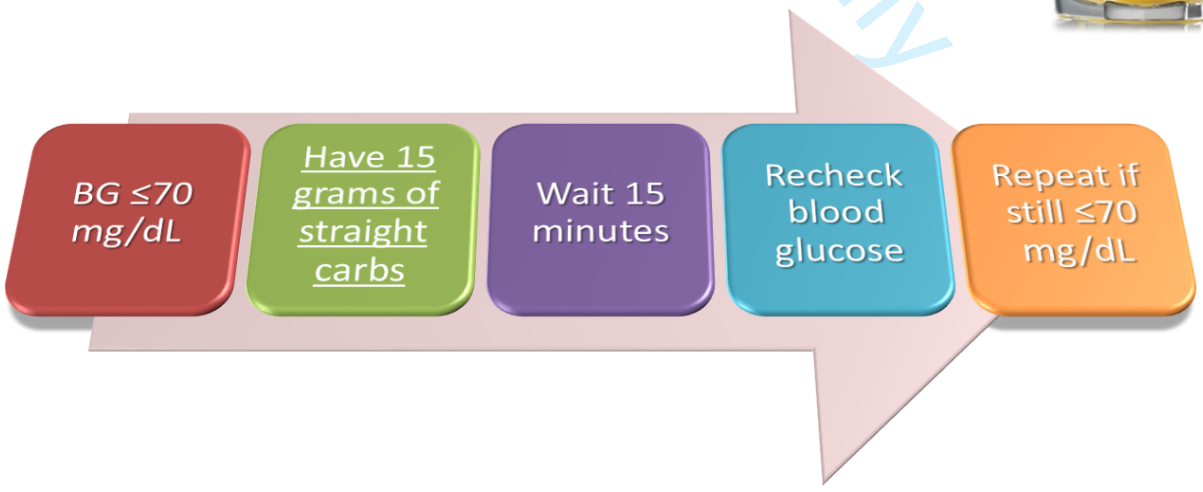
Low Blood Glucose:

1. If you take insulin, or a pill that makes your body release more insulin, you may be at risk for low blood glucose. When you lose weight or make healthier food choices, you may need less of your diabetes medication(s).

2. Symptoms of low glucose include shakiness, sweating, confusion, feeling weak and possibly hungry. If you feel these or any other unusual symptoms, check your CGM glucose reading. You may also want to confirm with a fingerstick test on your glucose meter.

3. To treat low glucose, you should eat/drink something with about 15 grams of carbohydrates/sugar. This might include ½ cup of juice, one cup of skim milk, or 3 to 4 glucose tablets. It will take at least 15 minutes for these sugars to work. If your glucose is still less than 70 mg/dL after 15 minutes, treat with another 15 grams of sugar.

4. If you have any readings less than 70 mg/dL, you should talk with your provider. Ask if you should reduce your medication(s) doses to prevent low glucose.



Dexcom CGM Real-Time (RT-CGM)

Your goals for the 3 months: Improve your glucose numbers and learn what food and activity does to your glucose!

1. Review at the following values on your Clarity App :
   - Pre-meal glucose average
   - Post-meal glucose average
   - Average Glucose f
2. Identify factors that resulted in the best and the worst glucose values.
3. Choose foods and activities that will improve your pre and post-meal glucose. Continue to record your food and activity, and pre and post meal glucose values on the log.

The people depicted are not patients and were taken with the participants knowledge.

UNIVERSIDAD DE WASHINGTON
FORMULARIO DE CONSENTIMIENTO
Compañeros en Salud y Monitorización Continua de Glucosa en Tiempo REAL

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Preguntas sobre el estudio: Evelin Jones, Coordinadora de investigación
Número telefónico: 206-221-9369

Declaración del investigador

Lo invitamos a participar en nuestra investigación. El propósito de este formulario de consentimiento es brindarle la información necesaria para ayudarle a decidir si desea participar en nuestro estudio. Favor de leer el formulario completo. Lo invitamos a hacer cualquier pregunta sobre nuestra investigación. Esperamos que al contestar todas sus preguntas, usted pueda decidir si desea participar en el estudio o no, ya que su participación en el estudio seria completamente voluntaria. Le daremos una copia de este formulario para sus registros. Este proceso se llama "consentimiento informado".

INFORMACIÓN IMPORTANTE DEL ESTUDIO

El estudio "Compañeros en Salud" con monitoreo continuo de glucosa comparará cómo funciona un programa de educación sobre la diabetes apropiado a la cultura Latina, en inglés y español, con y sin un dispositivo de monitoreo continuo de glucosa (azúcar) (CGM).

¿POR QUÉ ESTAMOS HACIENDO ESTE ESTUDIO Y QUÉ SE LE PEDIRÁ HACER SI PARTICIPA?

Al realizar este estudio, esperamos aprender si la intervención educativa ayuda a mejorar el cuidado de la Diabetes. Al mismo tiempo, estamos interesados en aprender si el monitoreo continuo de azúcar, y la intervención educativa juntas pueden tener mejores resultados en el control de la diabetes. Usted recibirá educación sobre la diabetes y puede ser asignado a un grupo el cual tendrá el dispositivo de monitoreo de los niveles de azúcar en sangre en tiempo real (RT). El segundo grupo también recibirá el programa de educación, pero puede que no reciba el dispositivo para monitorear los niveles de azúcar en tiempo real.

¿Cuál serían algunas razones para no PARTICIPAR EN ESTE ESTUDIO?

Se le pediría atender clases para aprender sobre el manejo y control de la diabetes. Es posible que prefiera simplemente continuar trabajando con su médico de cabecera en controlar su diabetes y no recibir educación sobre diabetes. También es posible que no esté interesado/a en recibir el dispositivo de monitoreo continuo de glucosa. Se le asignará

aleatoriamente para utilizar o no un CGM en tiempo real. Esto será decidido al azar, no por usted ni por el equipo de estudio.

¿CUALES SON ALGUNAS RAZONES PARA PARTICIPAR EN ESTE ESTUDIO?

La educación sobre la diabetes puede ayudar a mejorar su diabetes y ayudarle a vivir una vida saludable. Además, el dispositivo de monitoreo continuo de glucosa (CGM) puede ayudarle a mejorar el control de diabetes aún más de lo que ya lo está haciendo.

¿TIENE QUE PARTICIPAR EN EL ESTUDIO?

No, no tiene que participar en el estudio. Si decide participar en el estudio, debe ser porque realmente desea ser voluntario. Si decide no hacerlo, no perderá ningún servicio, beneficio o derecho que ya tiene y seguirá recibiendo tratamiento para su diabetes. También es importante que usted sepa que puede retirarse en cualquier momento durante el estudio.

¿Y SI QUIERE MÁS INFORMACIÓN?

El resto de este documento le brinda más información sobre el estudio, incluyendo:

- Qué se hará en las visitas de investigación
- Los riesgos del estudio
- Quién pagará el tratamiento si se lesiona por los procedimientos del estudio
- Cómo protegeremos su privacidad
- Con quién hablar si tiene problemas, sugerencias o inquietudes

PROPÓSITO DEL ESTUDIO

Este estudio proporcionará un programa de educación sobre diabetes apropiado a la cultura Latina, en inglés y español. Algunos participantes usarán un monitor continuo de glucosa (CGM). Queremos saber si la educación sobre la diabetes ayuda a reducir los niveles de azúcar, y si el monitoreo continuo de glucosa lo hace aún más útil.

PROCEDIMIENTOS DE ESTUDIO

El estudio se llevará a cabo a través de clínicas de salud de Sea Mar, clínicas de la Universidad de Washington y de la comunidad. El estudio incluirá a 100 personas con diabetes tipo 2.

Puede negarse a responder cualquier pregunta, prueba, inventario, cuestionario o entrevista.

Se le asignará aleatoriamente a **uno de dos grupos:**

1. Este grupo recibirá educación sobre diabetes de Compañeros en Salud sin el monitoreo continuo de la glucosa (CGM).

- Se le pedirá que use un CGM que esté **cegado:** Esto significa que no le mostrará sus números de azúcar en la sangre hasta el final del estudio.
- Usted continuará analizando su nivel de azúcar en la sangre usando su medidor de glucosa como lo recomiende su doctor de cabecera.

2. Este grupo recibirá educación sobre diabetes de Compañeros en Salud con el monitoreo continuo de la glucosa (CGM).

- Se le pedirá que use un CGM que no esté **cegado:** Esto significa que le mostrará sus números de azúcar en la sangre en tiempo real (RT), a medida que están sucediendo.
- El grupo en el que se encuentra se decide al azar (como lanzar una moneda al aire). Tiene las mismas posibilidades de estar en cualquiera de los dos grupos.

¿Qué es un dispositivo de monitoreo continuo de la glucosa (CGM)?

El monitoreo continuo de glucosa (CGM) es una forma de medir el nivel de azúcar o glucosa en la sangre. El dispositivo funciona de la siguiente manera: Guarda los números de azúcar en la sangre para que pueda verlos todo el tiempo (en tiempo real) o puede verlos más tarde. El dispositivo (CGM) tiene un filamento delgado y flexible que se inserta debajo de la piel y solo requiere un pinchazo en la piel. Los lugares del cuerpo donde se puede poner el dispositivo son los siguientes: puede usarlo en el estómago, brazo o gluteo. Una vez que está colocado, el dispositivo puede permanecer allí por 10 días. Un transmisor pequeño es usado sobre la piel donde está colocado el dispositivo para registrar los valores de azúcar. El dispositivo entero es aproximadamente del tamaño de una pequeña galleta. El transmisor envía los resultados de glucosa de forma electrónica a un teléfono inteligente o a un dispositivo donde podrá verlos inmediatamente, o más tarde.

También puede utilizar una aplicación de teléfono celular llamada Dexcom Clarity. Esta aplicación puede compartir sus números de azúcar en la sangre con el equipo de investigación. También puede optar por compartir estos números con un miembro de su familia, pero solo si usted lo desea. Para compartir los niveles de azúcar en la sangre, su familiar también deberá usar la aplicación y tener su permiso para ver sus niveles de azúcar.

Le daremos todos los materiales que necesitará. Tendrá un sobre con franqueo pre pago para devolver el dispositivo por correo al final de los 10 días. Si no puede enviarlo por correo, un Navegador del Paciente (Patient Navigator), anteriormente conocido como trabajador de salud comunitario (CHW) o educador de salud (HE) puede ir a su casa para recogerlo o puede llevarlo a la clínica.

A veces, un CGM puede caerse accidentalmente o dejar de funcionar antes del final de los 10 días. Si esto sucede dentro de los primeros 3 días, le daremos un nuevo CGM.

¿Cuánto tiempo dura el estudio y qué debo hacer?

Su participación en el estudio será por 6 meses **con las siguientes visitas:**

- 3 visitas de investigación programadas (1-1.5 horas cada una),
- 1 visita con el navegador del paciente o educadores de salud para enseñanza (1-1.5 horas), que podría ser junto con la primera visita del estudio,
- 12 clases de diabetes (1-1.5 horas cada una, ofrecidas en diferentes momentos en inglés y español) con un tiempo total de participación en el estudio de aproximadamente 25 horas.

Si desea participar en este estudio, le pediremos que lea y firme este documento de consentimiento antes de darnos algún dato. Las visitas de investigación se llevarán a cabo a través de telemedicina en su hogar o, si lo prefiere, en una Clínica local de Sea Mar o de la Universidad de Washington. Puede optar por hacer parte de las visitas en su casa y parte en una clínica.

Si firma este formulario en línea, se le enviará por correo electrónico una copia del formulario de consentimiento a una dirección de correo electrónico que proporcione. Será un documento "PDF". La mayoría de las computadoras ya tienen instalado el software de PDF, que le permitirá abrir, leer o imprimir el formulario de consentimiento. El correo electrónico que le enviemos incluirá un enlace al software de PDF (como Adobe Acrobat Reader) en caso de que su computadora aún no lo tenga. Sin costo alguno usted puede recibir una copia impresa del formulario de consentimiento. Si desea retirar su consentimiento, comuníquese con el coordinador de la investigación en la página 1 de este formulario de consentimiento.

También le pediremos que proporcione información de un contacto (número de teléfono, dirección, correo electrónico e información de contacto de familiares y / o amigos). Nosotros solo utilizaremos esta información para contactarlo acerca de las clases, las visitas, y para obtener los datos dados por el dispositivo que mide sus niveles de glucosa.

Después de firmar este consentimiento informado, le mediremos su hemoglobina A1C por medio de una punción en un dedo. Este análisis de sangre nos da un promedio de su nivel de azúcar en la sangre de los últimos 2-3 meses. Si usted es mujer, también le pediremos una prueba de embarazo en orina, ya que nuestro estudio no incluirá a mujeres embarazadas. Si la visita inicial no es en persona, es posible que le pidamos que vaya al laboratorio para una muestra de sangre y una prueba de orina. No puede participar en el estudio si su A1C es inferior a 8.0 o si está embarazada. Si durante el periodo del estudio usted llegase a quedar embarazada, usted continuará su diabetes y atención del embarazo con su proveedor de atención médica, y no continuará en el estudio.

1. <u>Visita 1: Detección y recopilación de datos</u>

- Se lleva a cabo 2-4 semanas antes de la primera clase de diabetes
- Tardará de 1 a 1,5 horas en completarse
- Mediremos su altura, peso, presión arterial y circunferencia de la cintura (usando una cinta métrica alrededor de su cintura).
- Le haremos preguntas sobre su diabetes, su salud y sus hábitos.
- Le asignaremos aleatoriamente a las clases de diabetes <u>con o sin</u> CGM.
- Le diremos las fechas de las 12 clases semanales (en español o inglés).

- Le pediremos que use un app en su teléfono para contar sus pasos y así medir cuanto camina, Si no tiene un app en su teléfono, le daremos un dispositivo llamado podómetro y le mostraremos cómo usarlo. Le pediremos que use el podómetro o mantenga su teléfono con usted mientras está despierto tanto como sea posible durante el estudio.
- Le daremos una tarjeta de regalo de $ 50.00 al final de la visita.

2. <u>Visita de seguimiento con un Navegador del Paciente (PN) , un educador de salud (HE) o personal del estudio.</u>

El mismo día de la primera visita del estudio o en otro momento, en su casa o en la clínica local, antes de comenzar las clases de diabetes, un Navegador del Paciente (PN) o educador de salud (HE) o personal del estudio, lo visitará o usted puede ir a verlo en una clínica local para que:

Le ayuden con Zoom y acceso a Internet. Si usted no tiene acceso a internet en su casa, le proveeremos con un dispositivo con acceso a internet para que use durante las 12 clases. También le mostrarán cómo insertar el CGM. Le ayudarán a resolver problemas comunes que las personas a veces tienen al usar los CGM.

Si está en el grupo de tiempo real (RT-CGM), el Navegador del Paciente/ HE lo ayudará a instalar la aplicación Clarity en su teléfono que necesitará para usar el dispositivo. Le mostrarán cómo compartirlo con los miembros de la familia si así lo desea. El Navegador del Paciente / HE también hablará con usted sobre cómo los alimentos y la actividad física afectan su nivel de azúcar en la sangre. Le enseñarán cómo usar el CGM para ver sus niveles de azúcar en la sangre y lo ayudarán a comprender lo que significan los números.

El Navegador del Paciente /HE le dará un registro de alimentos y actividades. Si elige una visita de telemedicina / Zoom, el Navegador del Paciente /HE puede preguntarle si puede verlo en persona para hacer mediciones (A1C y mediciones corporales).

Después de la visita 1, todos los participantes en ambos grupos usarán un CGM ciego durante 10 días. Esto significa que no verá sus números de azúcar en la sangre. Luego devolverá el CGM en la primera clase de diabetes en persona, o puede enviarlo por correo.

Si no obtiene un CGM, continuará controlando sus valores de azúcar según lo recomendado por su médico mediante una punción en el dedo.

3. <u>Clases de Educación: Clases compañeros en salud</u>

A continuación, asistirá a clases semanales de educación sobre la diabetes durante 12 semanas.

Estas serán clases grupales una vez a la semana a través de tele salud / Zoom o en un aula de Sea Mar. Usted estará en la clase con otras personas que tienen diabetes tipo 2. Le pediremos que asista a las 12 clases. Cada clase durará 1-1.5 horas. Le daremos todos los materiales para cada clase.

Estas clases utilizarán la plataforma Zoom. Las clases se grabarán para que pueda verlas más tarde. Antes de unirse a cada clase, verá un mensaje que dice que la sesión será grabada. Además, aunque le animamos a que aparezca en cámara durante las clases, no tiene que hacerlo. Puede elegir mostrar u ocultar su cámara.

Al final de la primera clase, las personas que estén en el grupo de monitoreado en tiempo real (RT-CGM), recibirán 15-30 minutos de educación sobre comida y actividades y como ver lo que está pasando con su azúcar en el CGM. Les mostraremos como empezar a usar el dispositivo CGM al final de esta clase, los Navegadores del Paciente / HE o personal del estudio quizá lo contacten al día siguiente para asegurarse de que no esté teniendo ningún problema usando el dispositivo.

4. Visita de estudio 2

Al final de las 12 clases, haremos lo siguiente:

- Le haremos preguntas sobre su diabetes
- Mediremos una A1C para ver cómo han sido sus niveles de azúcar en la sangre
- Haremos las mismas mediciones corporales que hicimos en su primera visita.
- Le entregaremos una tarjeta de regalo de $ 50.00 al final de la visita.

- Si no está en el grupo de CGM en tiempo real (RT-CGM):
  - Usted usará un CGM ciego una vez más durante 10 días, empezando 3 dias antes de la clase 11, el cual va a devolver después de 10 días. Si se olvida, lo puede empezar a usar lo antes posible.
  - El Navegador del Paciente /HE o el personal del estudio de investigación lo ayudarán a insertar el CGM ciego a través de telemedicina o en persona si es necesario.
  - Usted no verá sus niveles de azúcar en la sangre

- Si está en el grupo CGM en tiempo real (RT-CGM):
  - Usará el RT-CGM una vez más durante 10 días, comenzando 3 días antes de la clase 11. Si se olvida, lo puede empezar a usar lo antes posible.
  - Podrá ver sus niveles de azúcar en la sangre a medida que ocurren.

Después de la visita número dos, continuará trabajando en su diabetes con su médico de atención primaria. Las clases de diabetes y el uso de RT-CGM habrán terminado. Debe preguntarle a su médico si tiene alguna pregunta sobre su diabetes.

5. Visita de estudio 3

Esta visita será 3 meses después de la última clase de diabetes.

Pediremos a todos los participantes que usen un sensor cegado durante 10 días. Esta será la última vez que lo usarán. Le haremos las mismas preguntas que le hicimos en sus otras visitas. También mediremos la A1C y las medidas corporales.

¿Cuándo usa el RT-CGM?

Si está en el grupo de dispositivos de monitoreo continuo de glucosa en tiempo real (RT-CGM), después de su primera clase de diabetes, comenzará a usar el dispositivo durante un total de cinco ciclos de 10 días de uso. Recibirá 2 sensores adicionales en caso de que el CGM se caiga o se salga antes.

- Comience a usar el RT-CGM una vez que complete su primera clase de diabetes. Usar durante 10 días.
- Luego deje de lado durante 7 días
- Luego vuelva a usarlo durante 10 días
- El ciclo de uso es durante 10 días, luego descanso durante 7 días y luego de uso durante 10 días hasta que haya completado un total de 50 días (5 sesiones) de uso del sensor.
- El objetivo es iniciar el último sensor 3 días antes de la clase educativa número 11 y usarlo por 10 días.

Esta tabla muestra el programa de visitas, la información que se recopilará y el programa de uso de CGM para cada grupo.

Tipo de Visita	Detección y Visita 1 (Primera Visita)	Visita 2	Visita 3
Semana de estudio	Semana Cero	Semana 12*	Semana 24*
Lea y firme el consentimiento informado	X		
Contacto de emergencia	X		
Prueba de embarazo en orina (Mujeres)	X		
Datos demográficos	X	X	X
Medicamentos, historial médico	X	X	X
Cuestionarios	X	X	X
Análisis (Prueba) de sangre por punción digital HbA1C	X	X	X
Presión arterial, pulso, altura (estatura), peso, medidas de cintura	X	X	X
Podómetro durante 10 días	X	X	X
Visita del navegador del paciente	X		
Asignación aleatoria al grupo CGM	X		
Grupo CGM cegado	CGM Cegado 10 días	CGM Cegado 10 días	CGM Cegado 10 días
Grupo RT-CG	CGM Cegado 10 días	**RT-CGM** (cinco ciclos durante 10 días, siete días de descanso)	CGM Cegado 10 días
12 semanas de clases de diabetes		X	X
Encuesta a miembros de la familia (ambos grupos)	X	X	

Tarjeta de regalo de $50	**X**	**X**	**X**

* dentro de 2 semanas de esta fecha.

Despues de completar el estudio, al final de la visita 3, le ofreceremos a los participantes del grupo control/ciego que expresen interés, la posibilidad de usar 3 sensores Dexcom en Tiempo Real mientras tengamos suficientes suministros. No tendrá que pagar por estos sensores. Los datos recolectados por estos dispositivos no se utilizarán en el estudio, y el equipo del estudio no tendrá acceso a estos datos.

Si recibe estos 3 sensores, será responsable de informar todos los valores de glucosa recopilados por estos dispositivos a su equipo clínico de Seamar, y deberá comunicarse con este equipo si tiene problemas o preguntas sobre el uso de los sensores.

RESPONSABILIDADES

Clases de Compañeros en Salud (Ambos Grupos)
Es importante que complete todas las visitas del estudio, los procedimientos y las clases para ayudarnos a saber qué tan útil será el programa de educación sobre la diabetes.

CGM Cegado: Todos los participantes en ambos grupos usarán un dispositivo CGM cegado 10 días antes de la primera clase de diabetes, después del final de la última clase y nuevamente 3 meses después.

Clases de Compañeros en Salud con RT-CGM
Si está en el grupo de CGM en tiempo real, es importante que use el RT-CGM en los momentos programados para que podamos aprender qué tan útil es el CGM. Le pediremos que use el CGM durante 10 días, en 5 sesiones durante 12 semanas. Si no puede usar el CGM, comuníquese con el personal del estudio.

Participación de los miembros del hogar:
Si tiene hijos mayores de 8 años, cónyuge/pareja u otros miembros del hogar:

- Preguntaremos si estarían dispuestos a completar un cuestionario de menos de 10 minutos sobre sus hábitos alimenticios y actividad.
- Si se le asigna al grupo RT-CGM, les haremos algunas preguntas sobre el CGM (si son mayores de 13 años).

Para los miembros del hogar mayores de 17 años, si no están presentes durante su visita, le preguntaremos si está bien que los llamemos. Si está de acuerdo, les haremos preguntas por teléfono o correo electrónico. Le preguntaremos cuál es la mejor hora para comunicarnos con el miembro de su hogar. NO se recolectará información personal de salud sobre los miembros del hogar. El nombre, la relación con usted, la edad, el correo electrónico y el número de teléfono solo se utilizarán para contactar a los miembros del hogar que usted crea que podrían estar interesados.

No acepto que los miembros de mi hogar participen____

Acepto que los miembros de mi hogar participen si así lo desean____

Junta Asesora
Se solicitará a un número pequeño de participantes que formen parte de un consejo asesor. Esperamos mejorar las clases de diabetes y discutir cualquier desafío que las personas puedan tener al participar en las clases de diabetes y en las sesiones de telemedicina. Le pediremos a los 3 primeros participantes que se inscribieron y también a los 2 primeros participantes que dejaron de ir a las sesiones que formen parte del consejo asesor. Si estos eligen no participar, continuaremos preguntando al siguiente participante inscripto hasta que tengamos 3 participantes que hayan asistido a las sesiones educativas y 2 participantes que hayan dejado de asistir a las sesiones. Le haremos preguntas ya sea en un entorno grupal o individual, ya sea por tele-visita /zoom o por teléfono acerca de vivir con diabetes y cualquier barrera o dificultad que experimente. Las entrevistas durarán aproximadamente entre 45 a 60 minutos y se grabará el audio para garantizar que todas las respuestas sean entendidas/ recopiladas para luego resumirlas de manera general para abarcar a todos los participantes.

RIESGOS, ESTRÉS O INCOMODIDAD (MALESTAR)
¿EXISTEN RIESGOS EN ESTE ESTUDIO?

Los riesgos relacionados con su atención médica normal no se enumeran en este formulario. Le recomendamos que hable sobre esto con su médico del estudio, su proveedor de atención primaria u otro profesional de la salud.

Participar en una investigación implica algunos riesgos de daño o malestar físico o psicológicos. Siempre existe la posibilidad de que ocurran lesiones desconocidas o inesperadas.

Los riesgos más probables de este estudio se describen a continuación:

Monitoreo Continuo de Glucosa
El sensor CGM puede causar dolor cuando se inserta en la piel, como una inserción en el sitio de la bomba de insulina o una inyección de insulina. En raras ocasiones, puede ocurrir una infección de la piel en el sitio de inserción del sensor. Puede ocurrir picazón, enrojecimiento, sangrado y moretones en el sitio de inserción. Una alergia a la cinta que sujeta el sensor a la piel es posible. El riesgo de un problema en la piel podría ser mayor si usa un sensor durante más tiempo del que se supone que se debe usar. Existe la posibilidad de que el sensor o la aguja se rompan debajo de la piel. No se espera que esto ocurra, pero si ocurre, debe preguntarle al médico del estudio qué hacer.

Al igual que los glucómetros, o medidores de glucosa en sangre, que puede usar actualmente, es posible que el dispositivo CGM no proporcione una lectura precisa. Esto puede suceder debido a un mal funcionamiento, problemas con la batería o al apagar accidentalmente las alarmas. Si siente que la lectura de azúcar en la sangre de su CGM es diferente, debe revisar su nivel de azúcar en la sangre con el monitor de glucosa que su proveedor de atención primaria le haya proporcionado previamente para su control de la diabetes.

El uso de acetaminofeno (Tylenol) puede dar lecturas inexactas si toma más de la dosis recomendada de 3000 mg al día. Le recomendamos no tomar más de la dosis recomendada por día de este medicamento.

Con el dispositivo CGM, es posible que se sienta incómodo o inseguro sobre el uso de un dispositivo médico en su cuerpo durante 10 días seguidos.

Riesgo de Hipoglucemia e Hiperglucemia
Como una persona con diabetes, siempre existe el riesgo de tener un nivel bajo de azúcar en la sangre (hipoglucemia) o un nivel alto de azúcar en la sangre (hiperglucemia). Los síntomas de un nivel bajo de azúcar en la sangre pueden incluir sudoración, debilidad, temblores y no sentirse bien. Los síntomas de un nivel alto de azúcar en la sangre pueden incluir aumento de sed, cansancio, visión borrosa e irritabilidad. Las clases de diabetes le enseñarán cómo evitar niveles bajos de azúcar en sangre y qué hacer si esto sucede. Además, si ve niveles muy altos de azúcar, debe consultar a su médico de atención primaria para que lo ayude a controlar los niveles altos de azúcar.

Incomodidad de punción en el dedo
Cuando hacemos una punción en el dedo para la prueba A1C, es posible que tenga una ligera molestia en el sitio de la punción. Esto es similar a las punciones en los dedos que se hace cuando se mide el nivel de azúcar en la sangre. También existe el riesgo de mareos, moretones y posible infección con pinchazos en los dedos para la diabetes.

Cuestionarios y Medidas Clínicas
Le haremos preguntas sobre sus actitudes, sentimientos y comportamientos relacionados con la diabetes y en general. Aunque es poco común, es posible que algunas personas encuentren estas preguntas un poco molestas. Puede negarse a responder cualquier pregunta que lo haga sentir incómodo(a). Puede decidir no contestar preguntas, tomar un descanso o dejar de participar en el estudio en cualquier momento. Se tomarán muchas precauciones para mantener su información confidencial, pero esto no es una garantía.

Las clases de diabetes se brindarán virtualmente por Zoom, o en persona en una clínica de Seamar asignada. Los Navegadores del Paciente y los educadores de la salud (HE) utilizarán las oficinas/espacios educativos de Sea Mar para dirigir las sesiones. Las sesiones nocturnas pueden llevarse a cabo desde la casa del educador usando un espacio privado para garantizar la privacidad de los participantes.

Pérdida de privacidad
Recopilaremos los números de azúcar en la sangre de los CGM que le daremos. Tendremos información detallada sobre su diabetes y hábitos diarios de salud. Algunas personas pueden sentirse incómodas con esto. El equipo del estudio verá sus datos de CGM. También veremos la información utilizada para crear cuentas de estudio para las descargas de datos de CGM. Debido a que las clases de diabetes se llevarán a cabo en grupo, otras personas que asistan a las clases pueden verlo(a) y escuchar las preguntas que hace o la información que comparte.

Manguito de presión arterial: El manguito de presión arterial puede causar una ligera molestia cuando se infla, pero se desinfla en segundos.

Junta Asesora y entrevistas individuales: Puede ser que se ponga nervioso o le sea avergonzante hablar sobre porque dejó de ir a las sesiones o las barreras que no le permiten acceder al cuidado de salud con respecto a la diabetes. Si comienza a experimentar stress o molestias hablando sobre esos temas, puede elegir no contestar las preguntas, o tomarse un descanso, o finalizar la entrevista.

ALTERNATIVAS A PARTICIPAR EN ESTE ESTUDIO

Si no participa en el estudio, usted continuará con su tratamiento actual para la diabetes y control de azúcar en la sangre. Lo alentamos a discutir sus opciones con el personal del estudio, su médico de atención primaria u otro profesional de la salud que esté familiarizado con la diabetes tipo 2. Hay otras clases educativas disponibles en Sea Mar y otros centros de salud para el control/educación de la diabetes. Sin embargo, actualmente el CGM no es pagado por el seguro en pacientes con diabetes tipo 2 que toman menos de 3-4 inyecciones de insulina al día. Si desea usar un dispositivo CGM fuera del estudio, su proveedor de atención primaria podría recetarlo, pero tendría que pagar el costo total del CGM de su bolsillo (cada sensor cuesta $35-70 según el tipo de dispositivo CGM que esté usando).

BENEFICIOS DEL ESTUDIO

Puede haber un posible beneficio médico para usted si decide participar en el estudio, pero no es una garantía. Es posible que no reciba ningún beneficio directo por participar en el estudio. Las personas que participen en este estudio de investigación agregarán nuevos conocimientos que pueden ayudar a otras personas con diabetes tipo 2.

CONFIDENCIALIDAD DE LA INFORMACIÓN DE LA INVESTIGACIÓN

Toda la información que proporcione será confidencial. Sin embargo, si nos enteramos de que tiene la intención de lastimarse a sí mismo o a otros, debemos informarlo a las autoridades.

El personal del gobierno o de la universidad a veces revisa estudios como este para asegurarse de que se realicen de manera segura y legal. Si se lleva a cabo una revisión de este estudio, es posible que se examinen sus registros. Los revisores protegerán su privacidad. Los registros del estudio no se usarán para ponerlo en riesgo legal de sufrir daños.

OTRA INFORMACIÓN

¿QUÉ SUCEDE SI QUIERO RETIRARME DEL ESTUDIO O SE ME PIDE RETIRARME DEL ESTUDIO?

Puede negarse a participar y puede retirarse de este estudio en cualquier momento sin penalización ni pérdida de los beneficios a los que tiene derecho. Puede continuar recibiendo

atención médica no relacionada con este estudio. Le animamos a que hable con un miembro del grupo de investigación, para que ellos sepan por qué está interrumpiendo el estudio. Su decisión no generará ninguna penalización ni pérdida de atención médica. Puede continuar recibiendo atención médica no relacionada con este estudio. También podemos pedirle que participe en la junta asesora o que haga una entrevista de salida para que podamos aprender cómo mejorar el programa.

Si está embarazada, la retiraremos del estudio y no recopilaremos más datos. Le pediríamos que busque atención de su proveedor de atención primaria.

Devolviéndole los resultados

Recibirá los resultados de las pruebas de laboratorio (A1c). También podrá ver su nivel de azúcar en la sangre en tiempo real si está en el grupo RT-CGM. Si no está en el grupo RT-CGM, los educadores de salud de Seamar recibirán sus valores de azúcar en sangre al final del estudio y es posible que pueda revisar los resultados con su médico. Si dice en el cuestionario inicial que tiene algún pensamiento acerca de hacerse daño, lo llamaremos de inmediato y lo ayudaremos a obtener ayuda.

¿HAY COSTOS RELACIONADOS CON LA PARTICIPACIÓN EN EL ESTUDIO?

El estudio pagará solo por las pruebas relacionadas con el estudio. Los costos del tratamiento, visitas al consultorio y pruebas para su diabetes y otras condiciones médicas serán responsabilidad suya o de su compañía de seguros. Esto se considera un cuidado estándar.

El estudio pagará los costos de todos los suministros y procedimientos de investigación que tendrá específicamente para el estudio. Estos incluirán los materiales educativos y el sistema de CGM, sensores, y un podómetro si es necesario. Ocasionalmente, puede ver un mayor uso de datos o una pérdida más rápida de batería en su teléfono inteligente con el uso de la aplicación CGM (Clarity). Si esto sucede, notifique al equipo de investigación para que podamos ayudarlo con este problema.

Compensación

Si participa en el estudio, recibirá una tarjeta de regalo de $50 por cada visita de colección de datos, por un total de $150 si completa las tres visitas de colección de datos. Si se requieren visitas adicionales no programadas, puede recibir hasta $50 adicionales.

El miembro de su hogar también recibirá una tarjeta de regalo de $15 por completar la encuesta/cuestionario. Si se le pide que forme parte de una junta asesora para mejorar el programa de educación y la telemedicina, usted y el miembro de su hogar también recibirán una tarjeta de regalo de $50 por cada hora que pasen en la junta asesora (probablemente $100 por cada reunión o $200 dólares en total). Usted recibirá $50 por cada hora en la que usted participe en entrevistas de 1:1.

Como incentivo adicional por asistir a las sesiones educativas, se entregara una tarjeta de regalo por $25 por asistir a 4 sesiones educativas o más, Se entregara otra tarjeta de regalo por $25 por asistir a 8 sesiones educativas o más.

¿A quién puedo llamar si tengo preguntas, quejas o si estoy preocupado(a) por de mis derechos como participante?

Si cree que tiene un problema médico o una enfermedad relacionada con esta investigación, comuníquese de inmediato con la Dra. Nicole Ehrhardt o con otro miembro del equipo de investigación al número que se proporciona en este documento. Ella lo tratará o lo referirá para que reciba tratamiento.

Si tiene alguna pregunta sobre sus derechos como sujeto de investigación u otras preguntas, preocupaciones o quejas sobre la investigación o su participación en este estudio, debe comunicarse con la División de Sujetos Humanos de la UW al (206) 543-0098 o llamar por cobrar al (206) 221-5940.

Uso de datos y muestras

La información y/o las muestras que obtengamos de usted para este estudio podrían utilizarse para estudios futuros. Podemos eliminar cualquier cosa que pueda identificarlo de la información y las muestras. Si lo hacemos, esa información y muestras pueden usarse para futuros estudios de investigación o entregarse a otro investigador sin obtener un permiso adicional de su parte. También es posible que en el futuro queramos usar o compartir información del estudio que pueda identificarlo. Si lo hacemos, una junta de revisión decidirá si necesitamos o no obtener un permiso adicional de su parte.

Fuente de Financiamiento

Este estudio de investigación cuenta con el apoyo de una subvención de la Asociación Estadounidense de Diabetes. Además, Dexcom (el fabricante del dispositivo CGM que se utiliza en el estudio) ha proporcionado suministros de CGM a un costo reducido para el equipo del estudio.

Declaración del sujeto:

He leído este formulario de consentimiento y se me ha explicado el estudio de investigación. Mis preguntas han sido contestadas a mi satisfacción. Entiendo que al firmar este formulario, no he renunciado a mis derechos legales ni liberado a nadie de negligencia. Elegí ser voluntario para el estudio. He recibido una copia de este formulario.

No firme este formulario de consentimiento a menos que haya tenido la oportunidad de hacer preguntas y haya obtenido respuestas satisfactorias.

Si accede a participar en este estudio, recibirá una copia firmada y fechada de este formulario de consentimiento para sus registros.

Declaración de consentimiento del presentador

Le he proporcionado a este participante información sobre este estudio. Al participante se le ha dado suficiente tiempo para considerar su participación y he respondido a todas las preguntas que tenían. El participante indicaron que comprenden la naturaleza del estudio, incluyendo los riesgos y beneficios de participar.

_____

Nombre impreso del personal del estudio que obtuvo el consentimiento Fecha

_____

Nombre impreso del sujeto Firma del sujeto Fecha

Copias a: Investigador
Sujeto
Expediente médico del sujeto (si corresponde)

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

Researchers: **Principal Investigator:** Nicole Ehrhardt, MD
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Contact person for subjects: Evelin Jones Research coordinator
Phone: 206-221-9369

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 <u>with</u> 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 **<u>with the following visits:</u>**

- 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. <u>Visit 1: Screening and Data Collection</u>

- 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 <u>with or without</u> 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.

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

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 <u>not</u> 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. <u>Study visit 3</u>

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.

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.

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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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	page 2 145
	2b	All items from the World Health Organization Trial Registration Data Set	page 1 and 2
Protocol version	3	Date and version identifier	Not including please indicate if shoudl be added
Funding	4	Sources and types of financial, material, and other support	page 1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	page 1
	5b	Name and contact information for the trial sponsor	N/a
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	None/N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A see data monitoring

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	page 4-6 148-216
	6b	Explanation for choice of comparators	page 5 180-183
Objectives	7	Specific objectives or hypotheses	page 6 217-223
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	page 7 226-229
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	page 7 236=238
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	table 1 page 7 -page 8 intervention : page 11 333-334
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	page 11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	page 12 373-378
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	page 12 373-378
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12 373-375
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	page 10-11 305-330 table 3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	scheme figure 1 446

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	page 8 251-264
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	page 8 265-304
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	page 7 227-229
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	page 7 227-229
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	page 227 to 234
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	page 7 231-234
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	305-312 page 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	page 10 308-309

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	page 9 230-231
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	page 7 226-304
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	page 9 226-304
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	page 9-10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	i do not think we have this??
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	page 7 230
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	page 7
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	page 2 98
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	page 13 398
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/q
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	consent form spanish and english
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effectiveness of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes: The CUT- DM with CGM for Latinx randomized controlled trial study protocol.

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Effectiveness of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes: The CUT- DM with CGM for Latinx randomized controlled trial study protocol.

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Abbreviations:

Persons of Latin American cultural or ethnic identity in the United States (Latinx)
Type 2 Diabetes (T2D)
Real-time continuous glucose monitoring (RT-CGM)
Diabetes self-management education and support (DSMES)
Federally Qualified Health Center (FQHC)
Hemoglobin A1C (A1c)
Health Educator (HE)
Community Healthcare Worker (CHW)
Research Electronic Data Capture (REDCap)
Certified Diabetes Educator (CDE)
Young Men's Christian Association (YMCA)

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Competing Interests: Dr. Ehrhardt has been on an advisory board for Dexcom, Bayer and Novo Nordisk and received investigator-initiated grants from Dexcom and educational grants from Merck and Novo Nordisk. Drs. Montour, Wright, Sinclair and Berberian, Bryan Comstock, Brian Cedeno and Gary Ferguson have nothing to disclose.

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Abstract

Introduction: The prevalence of type 2 diabetes (T2D) is increasing in the Latinx community. Despite telehealth and technology becoming more available, these resources are not reaching the Latinx population. Diabetes education is a cornerstone of treatment; however, access to culturally tailored content is a barrier to the Latinx population. Real-time continuous glucose monitoring (RT-CGM) is a patient-empowering tool that can improve glycemic control, but it is not readily available for Latinx patients with T2D. We aim to evaluate a culturally tailored diabetes self-management education and support (DSMES) curriculum, using a team-based approach to improve glycemic control, promote healthy behaviors and enhance patient access with the use of telehealth in Latinx individuals. The primary aim of the study is to evaluate the additive effectiveness of RT-CGM on glycemia and behavioral changes among Latinx patients undergoing a culturally tailored DSMES. A sub aim of the study is to evaluate family members' change in behaviors.

Methods: We propose a randomized controlled trial of blinded versus RT-CGM with 100 Latinx participants with T2D who will receive DSMES via telemedicine over 12 weeks (n=50 per group). The study will be conducted at a single large Federally Qualified Health Center (FQHC) system. The control group will receive culturally tailored DSMES and blinded CGM. The intervention group will receive DSMES and RT-CGM. The DSMES is conducted by community Health Educators (HE) weekly over 12 weeks in Spanish or English, based on participant's language preference. Patients in the RT-CGM group will have cyclical use with a goal of 50 days wear time. The primary outcomes are changes in A1c and CGM-derived metrics at 3 and 6 months. The secondary outcomes include participants' self-management knowledge and behavior and household members' change in lifestyle.

Ethics and dissemination: The study proposal was approved by the University of Washington ethics/ IRB Committee as minimal risk (IRB ID: STUDY00014396) and the Sea Mar IRB committee.

Trial registration number: ClinicalTrials.gov identifier: NCT05394844

Keywords: Diabetes and Endocrinology, Health Equity, General Medicine

Strengths and Limitations of Study:

⇒ Training in digital literacy is an integral part of the study.

⇒ Culturally tailored DSMES is delivered through a telehealth platform to increase geographic outreach.

⇒ All curriculum and behavior modification surveys are available in both English and Spanish.

⇒ This RCT maybe underpowered if retention is less than expected.

⇒ Behavior modification of participants' household members after DSMES with and without RT-CGM with no direct intervention targeting household members is also evaluated.

Introduction: The prevalence of diabetes in adults in the U.S. now exceeds 14%, with T2D accounting for 90-95% of all cases.[1] Diabetes incurs healthcare costs of over $200 billion annually in the U.S. alone[2] and is the leading cause of blindness, chronic kidney disease, heart disease, and amputations[3]. The Latinx population is disproportionately affected by T2D, with a prevalence that is 80% higher than in non-Latinx whites[4]. Latinx individuals with T2D experience higher rates of diabetes-related complications including retinopathy and chronic kidney disease[5] Latinx individuals with diabetes also face greater challenges accessing medical care and pharmacotherapies[6]. Diabetes Education is an integral part of diabetes self-care and empowerment. However, broader implementation of behavioral interventions has been limited to date by 1) lack of data-driven design, 2) inadequate patient access, and 3) absence of culturally tailored curricula that are essential for reaching specific populations[7,8]. Culturally tailored DSMES curricula are promising, but clinical data on optimal approaches for implementing these programs are limited, with a particular scarcity of data in Latinx populations[9,10].

The DSMES curriculum *Compañeros en Salud* (Partners in Health)[11] is a multi-cultural and bilingual 12-module program that was created specifically for Latinx populations to improve diabetes self-management. *Compañeros en Salud* was first tested in the Latinx population as five 2-hour sessions under the name "*El Camino a la Salud"* and has been evaluated in two previous studies[12-14]. In response to feedback on the initial curriculum, author Sinclair (formerly named Two Feathers) updated the name to *Compañeros en Salud* in order to highlight the "communal" strength in the Latinx population and changed the delivery to twelve 1-hour

sessions in order to increase focus. The 12-session hourly curriculum was first studied in Native Hawaiians and Pacific Islanders[15] and then piloted in an English-speaking Latinx population with in-person sessions in Seattle, WA[16]. DSMES is the foundation of diabetes self-management, but additional tools are needed to reinforce behavioral change and to support participants' self-empowerment. The use of RT-CGM is a highly effective intervention for improving glycemia in patients with type 1 diabetes[17-20], but its use in patients with T2D is limited, in part due to insurance barriers[21,22]. The American Diabetes Association's (ADA) guidelines highlight the utility of CGM for patients using non-insulin or basal insulin regimens[23]. We previously showed that cyclical RT-CGM use over 3 months significantly improved A1c in subjects with T2D not using prandial insulin[24] and that this improvement was sustained beyond the period of RT-CGM use[25]. Other studies using intermittent flash CGM technology and a multi-center CGM intervention in primary care clinics showed similar results[26,27]. A key factor behind these benefits may be behavior modification associated with RT-CGM, however, studies are lacking[28]. Despite these benefits, CGM is not readily available to many people living with T2D[21,22]. A small, single group pilot study with 15 Latinx adults evaluated the *Compañeros en Salud* DSMES curriculum and RT- CGM intervention in Seattle, WA[16]. The average baseline A1c of 9.3% improved to a post-intervention A1c of 8.5% ($p<0.01$). Participants lost an average of five pounds and there were significant improvements in systolic ($p=0.03$) and diastolic ($p=0.002$) blood pressure. Our exploratory data demonstrate both acceptance of and perceived benefit from RT-CGM in Latinx individuals with T2D. Telemedicine[29,30] offers a novel strategy for addressing the lack of access to diabetes education, one of the largest barriers to improving diabetes control and a common challenge for the Latinx population[7,8]. Telemedicine is often underutilized in populations such as those that identify as Latinx[31-33], as digital literacy and access to broadband internet are barriers that contribute to health inequalities in this population.

Beyond the impact of direct interventions on study participants, we are interested in the impact on other individuals in the participants' lives. Spouses and partners of individuals with diabetes are at increased risk for developing T2D[34-35]. Children are more likely to develop obesity if they have family members living with this disease[36] and have a 20-40% absolute risk for developing diabetes if they have a parent with T2D[37]. Diabetes in a family member has been shown to have a higher positive predictive value for developing T2D compared to obesity[38].

This elevated risk, particularly in Latinx communities, is thought to result from a combination of genetic and environmental factors including shared nutritional and physical activity behaviors[39,40]. Interventions that promote behavioral modification in an individual patient may have the potential to impact other members of the household**.** Family-based interventions are effective at reducing childhood obesity[41,42], a meta-analysis concluded that parent-only interventions are as effective as parent-child interventions for mitigating childhood obesity[43]. Studies have also demonstrated an effect on spouses not participating in the intervention[44-47]. This study has an exploratory objective to look at whether this intervention reaches household members in a so called "ripple" effect.

Aims and Objective*s:* The primary aim of this study is to determine the additive effectiveness of RT-CGM among Latinx T2D patients undergoing culturally tailored DSMES curriculum at improving glycemic indices (including A1c and CGM outcomes) at 12 and 24 weeks. The secondary objectives are to evaluate changes in blood pressure, lipid profile, waist circumference, medication adherence, lifestyle and diabetes distress changes and social determinants of health. A sub aim of this study is to explore whether a "ripple effect" on nutritional or activity behaviors is observed in household members.

Study Design

This study is a randomized controlled parallel group trial of DSMES with and without RT-CGM among Latinx patients with a diagnosis of T2D. Intervention assignments were generated (1:1 to either blinded CGM + Education or RT-CGM + Education) using permuted block randomization with block sizes of 2, 4, or 6. Randomization was stratified by baseline A1c (< 9.0 or ≥ 9.0) upon confirmed eligibility and consent using a REDCap database (Research Electronic Data Capture, Vanderbilt University). An independent study statistician generated the randomization lists and is unblinded, though has no direct involvement with patients or outcomes assessors. The RC, HEs, CHW and participants are unblinded to the intervention, but the PI and CO-I's are blinded to participants and their intervention. Outcome measurements are evaluated at baseline and after 12 and 24 weeks (figure 1).

Population*:* Participants in this study are Latinx patients with T2D who receive care from one large, federally funded health care system in the greater Seattle area. Initial review of the 6 main clinics where potential recruitment occurs showed >450 Latinx patients with A1c >8.0%.

Inclusion and Exclusion Criteria: The goal is to recruit those that identify as Latinx with poorly controlled T2D (A1c > 8.0%). See Table 1 for a full list of inclusion and exclusion criteria.

Recruitment: Patients are identified both by review of the most recent A1c documented in the electronic medical record and by screening clinicians' and health educators' (HEs) office visit schedules in search of patients with a diagnosis of T2D. Additionally, flyers distributed in the community at places of worship, Young Men's Christian (YMCA) facilities and other local community areas serve to further enhance community engagement. Participants are asked whether we may contact household members >8 years old to participate in 2-3 short surveys. Recruitment is quarterly and begins 1 month prior to each 12-week educational cycle. A total of 4-6 DSMES cycles are needed to reach 100 active participants, defined as those that complete at least 1 educational session.

Sample Size Estimation*:* We will enroll up to 130 participants to obtain a total of n=100 study participants who complete at least 1 educational session. The study is designed and sized first for assessing the change in A1c from baseline to 12 weeks among all study participants and secondarily to assess the impact of RT-CGM. To assess statistical power, we assume a standard deviation in baseline A1c of 1.2 and a reduced standard deviation of 1.0 at 12 weeks to reflect an anticipated reduction in A1c due to the *Compañeros en Salud* curriculum. We further assume a correlation in A1c measurements of r=0.5, which is likely to be higher, resulting in greater statistical power. Finally, assuming a 15% reduction in the effect sample size (n=85) due to attrition, the study is sized to detect reductions in A1c of 0.4% or larger with 90% statistical power. If the actual correlation between baseline and week 12 A1c measurements is r=0.7 or higher, the study has 90% power to detect differences in A1c as small as 0.3%. Under similar assumptions, the study is sized to detect a 0.6% difference in 12-week A1c between subjects randomized to RT-CGM vs. blinded CGM (power = 0.82 assuming r=0.5; power=0.93 assuming r=0.7). A two-sided type 1 error rate of 0.05 is assumed throughout.

Statistical Analysis: The primary endpoint is the change in A1c from baseline to 12+/-2 weeks (end of the intervention period). Secondary outcomes include between-group differences in change in A1c at 24+/-2 weeks and changes in body weight, BMI, and blood pressure at 12+/-2 and 24+/-2 weeks. We will use simple descriptive statistics to quantify between-group

differences in changes in CGM indices, including time in range (TIR) mean glucose, mean amplitude of glycemic excursions (MAGE), times above and below range (TAR and TBR), and coefficient of variation (COV). The primary outcome of A1c will be assessed using a random-intercept random-slope linear mixed effects regression model that adjusts for an indicator of RT-CGM and time (baseline, visit 2, and visit 3) as fixed effects. To assess the effectiveness of the *Compañeros en Salud* curriculum, inference for Aim 1 will focus on the change in A1c from baseline to 12 weeks for the entire cohort (regardless of RT-CGM status). Main secondary outcome measures will be TIR and mean glucose by CGM. Additional outcomes including body mass index, waist circumference, and systolic/diastolic blood pressure will be assessed similarly using a generalized linear mixed effects model appropriate for each type of outcome measurement. We will conduct a missing data analysis to describe and characterize enrolled participants who do not provide data due to attrition. Linear mixed effects models naturally handle intermittent missing data through maximum likelihood estimation. As described by Molenberghs and Kenward[48], we will use inverse probability weighting in secondary analysis within each longitudinal regression model to inflate the weights of cases that are underrepresented in the analysis due to selective attrition and/or non-participation. We will also conduct sensitivity analyses using 10-fold multiple imputation to assess the robustness of the results when missing data are imputed. The characteristics of non-responders will be summarized in our final report, and we will present the sensitivity of the estimated treatment effect due to alternative missing data methods.

The effect of wearing RT-CGM on CGM indices will be assessed using a similar analytic framework as with the analysis of A1c. The linear mixed model coefficient for RT-CGM will be coded to estimate the average difference in 12-week change in outcomes due to receiving real-time glucose data on the outcome of interest. The effectiveness of the *Compañeros en Salud* curriculum on glycemic outcomes, sugared beverage intake, steps/day, reported walking, and diabetes distress will be assessed both overall and by RT-CGM status, and models will additionally adjust for an indicator of survey language (English vs. Spanish). Finally, exploratory outcomes include changes in nutritional behaviors for household members, specifically sugared beverage intake. Secondary outcomes for household members will include perception of benefit for the household member not actively engaged in the intervention or wearing the CGM. The outcomes of household members will be measured and assessed similarly

but in separate generalized linear mixed effects models. For participants with involved household members, we will examine the associations of behavioral and dietary outcomes between participants and household members through direct adjustment of participant data in household member outcome models. We will explore temporal associations using time-lagged participant outcomes in the longitudinal model.

Data Collection: All data will be collected by HEs or CHWs and stored in REDCap (figure 2). CGM data will be reviewed and inputted by a study research coordinator. The following data will be collected from participants, when appropriate, using validated tools at baseline (Visit 1) and after the intervention period (3 months/Visit 2 and 6 months/Visit 3). Participants will be provided with compensation for each visit completed.

Patient demographics: Age, gender, presence of diabetes complications, co-morbidities, smoking status, alcohol use, medications, cohabitation, educational level, health insurance status, household income, access to internet and smart phone or personal electronic device will be collected directly from the patient.

Anthropometric, vital sign, laboratory, and pedometry measurements: Height will be measured by a stadiometer. Weight will be measured using a Digital scale, and BMI (kg/m^2) will be calculated. Waist circumference will be measured using a flexible measuring tape. Participants will remain in a seated position for a minimum of 15 minutes prior to measurement of resting heart rate and blood pressure with an Omron Professional Digital blood pressure and heart rate monitor. Current A1c will be assessed by DCA Vantage Analyzer at all visits. Participants will be given a pedometer or if preferred will use one available on their smartphone. CGM data will be collected for 10 days after the first visit and for the 10 days prior to each of visits 2 and 3.

Glucose/CGM Data /Evaluation Outcome Measures: For participants in both the education-only and RT-CGM study arms, the % time the CGM device was worn over each period of use will be captured. Glycemic outcome measures include time in range (TIR), mean glucose, coefficient of variation, mean amplitude of glucose excursion (MAGE), % time below range (TBR) (<70 mg/dL), and % time above range (TAR) (>180 mg/dL). Between-group comparisons for CGM-derived glycemic metrics will be assessed based on changes from baseline to study week 12 and baseline to study week 24.

Patient Reported Outcome Measures: Participants will be asked questions about nutrition, physical activity, depression, diabetes distress, self-care, food insecurity and neighborhood safety. See a full description in Table 2.

Patient /Public Involvement*:* The initial protocol was modelled after a telemedicine Diabetes Prevention Program completed by our community partner FQHC during the COVID-19 pandemic. We have completed the first cycle of the education intervention and 15% of first pilot cycle participants (including those who completed at least 50% of the education curriculum plus those who dropped out of the program) completed detailed interviewing with topics including: perceptions of the educational program, comfort using telemedicine, barriers to taking care of health/diabetes and participation/engagement in the intervention, and suggestions to increase enrollment and to improve cultural tailoring. These interviews will be repeated in cycle two to further adapt/improve the program. The Washington State Department of Health, the Washington State Health Authority and local Latinx community advocacy programs have been engaged early to support the program and to begin discussions about sustainability and replication

The Intervention:

The DSMES curriculum: *Compañeros en Salud[11]* entails 12 hour-long weekly educational classes that will be led by CDEs and HEs. The intervention emphasizes ADA clinical goals for blood glucose, A1c, blood pressure and lipids, and is designed to reduce risk factors associated with T2D complications by optimizing T2D self-management activities (Table 3). Target behaviors include healthy eating, physical activity, blood glucose monitoring, medication adherence, problem-solving, healthy coping, communicating with one's healthcare team, asking for support from family and friends, taking an active role in individual healthcare, and understanding what kind of T2D care is needed. The curriculum is written in a conversational tone in plain language that facilitates learning for participants with little formal education and ensures intervention fidelity. Group discussion, role-playing, problem-solving, and hands-on activities are included to encourage engagement and enhance learning. Sociocultural strategies, which present T2D in the context of cultural values and community characteristics, are incorporated to increase the intervention's salience to participants. For example, a facilitator

might begin a class with a story about ordinary community members with T2D, using culturally relevant metaphors to link their situation with effective self-management behaviors.

Medical Device: *CGM (DEXCOM (G6))[49]:* A continuous glucose monitor (CGM) is a tool that allows measurements of glucose levels in real-time throughout the day and night. A tiny electrode called a glucose sensor is inserted under the skin by a skin prick to measure glucose levels in tissue fluid for 10 days. The RT-CGM-education intervention group will wear the RT-CGM cyclically. The intervention participants will have RT-CGM data downloaded after 3 cyclic sessions of use and at 5 sessions of use and wear the CGM blinded at baseline and 24 weeks. The Blinded-CGM education group participants will wear the blinded CGM at baseline, at 12 weeks, and 24 weeks. CGM Ancillary Devices Dexcom CLARITY® is an accessory for users of the Dexcom CGM system and it allows the transfer of glucose data from the CGM system to Dexcom remote servers for data management to allow the use of the CGM data by the user and by study personnel. Additionally, if participants desire, the Dexcom G6 CGM System comes with a built-in Dexcom Share feature allowing up to 10 people to follow a participant's glucose levels, providing a circle of support. By downloading the Dexcom Follow app, followers can view participant's glucose data directly from their smart device. For participants who do not have a smart phone, one will be provided to them.

Education and Evaluation tools in Spanish: *Compañeros en Salud[50]*, CGM Education material and behavior modification questionnaires for CGM are in Spanish. The culturally tailored English educational materials[11] for the Latinx population have been piloted in a small English speaking Latinx population and have been translated to Spanish by the HE, native speaking research personnel and a Latinx physician on the research team who is also a native speaker[50]. A questionnaire for perception on how CGM affects/changes lifestyles[51] was previously developed and is now also available in Spanish (Supplementary Material 1). Finally, a RT-CGM educational handout to explain glucose goals and how food and activity affects blood sugar was developed by an endocrinologist team-member and diabetes educational specialist and is available in both English and Spanish (Supplementary Material 2 and 3).

The DSMES curriculum with and without RT-CGM is an adjunct to participants' current diabetes management in their primary care clinic which continues throughout the intervention and encourages engagement with their healthcare provider.

Digital Literacy: HE or CWH will engage participants no more than 4 weeks prior to the start of the DSMES intervention to ensure participants have a working technology platform for the education sessions and to provide smart phones with data plans if needed. For all participants, CHWs/HEs will teach simple CGM insertion (blinded and RT). For those who are enrolled in the RT-CGM arm, the CHWs/HEs will set up a mobile app for the RT-CGM device. HEs/CHWs will conduct a single 30-minute training session on CGM for participants in the study, with particular focus on the use of RT-CGM as a tool to understand the impact of food and activity choices. The DMSES curriculum *Compañeros en Salud* will be led by the HEs weekly and will take place on a digital platform and are encouraged but in person sessions are available. Sessions are recorded but live attendance is strongly encouraged.

Ethics and Dissemination: The study proposal was approved by the University of Washington ethics/ IRB Committee (IRB ID: STUDY00014396 date 1/7/2022) and the Sea Mar IRB committee and funded by the American Diabetes Association Disparities of Health Care grant 11-21-ICTSHD-51. The findings will be published in peer-reviewed journals and presented at scientific conferences. All recruited patients will be informed by the HE/CHW, verbally and in writing, about the objectives, methodology, tests, and interventions they receive if they participate in the study. Patients will be included if they grant permission and sign the informed consent. Household members will give verbal assent. The consent document is available in both Spanish and English (Supplementary Materials 4 and 5). All participant information will be stored on REDCap. Any modifications to the protocol will require a formal amendment to the protocol and acceptance by the ethics committee. We plan to publish the findings in peer-reviewed journals and share our findings at scientific conferences. The investigators will consider authorship following widely accepted criteria.

Limitations of the Study:

This study is limited due to involving only a single center and smaller sample size. All participants receive an intervention with DSMES to enhance diabetes knowledge. We believe that those that receive RT-CGM with DSMES may have better initial diabetes indices after the DSMES intervention is completed given real-time feedback from CGM, and sustained improvement at 6 months without further intervention. However, the study may be

underpowered if retention is less than expected. We will aim to recruit up to 130 participants given a likely 20-30% drop out prior to education given the population served. This estimate is based on experience by the community partner with other diabetes education programs. We additionally do not have funding to evaluate longer-term effects (>1 year). While there may be initial improvement after intervention at 3 months and 6 months, long-term follow-up will need to be explored in future studies. Finally, although culturally tailored interventions are important, due to the heterogeneity within the Latinx population, adapting a single educational curriculum to reach all Latinx participants from many different backgrounds remains a challenge. We intentionally elected to use HE's and a bilingual bicultural physician working in the local community as the primary translators of the curriculum, with the purpose of capturing cultural nuances that may benefit communication with the participants. A formal translation service was not utilized, and we recognize that this could also be a potential limitation.

Table 1: Inclusion and Exclusion Criteria

Inclusion criteria:	**Exclusion Criteria:**
Participants must be 18 to 60 years old	Duration of diabetes > 15 years
Self-identify as Latinx.	Type 1 diabetes or latent autoimmune diabetes
A clinical diagnosis of T2D within the last 15 years with or without medication use	Current use of prandial insulin
A1C ≥8.0% at screening	Any condition that prevents walking at least 1 city block
Be physically and cognitively able to use the home CGM monitoring device	History of serious mental illness other than adequately treated depression
Be willing and able to follow all study procedures	History of bariatric surgery or current participation in a weight management program
	Current diagnosis of cancer or other serious or systemic medical condition or significant active cardio- or cerebrovascular disease after review by PI
	Pregnancy
	Known history of hypoglycemia unawareness

Table 2: Weekly Education Session Topics for *Compañeros en Salud.*

Session	Topic
1	Glucose Balance
2	Diabetes Medication
3	Food
4	Diabetes Diets
5	Exercise
6	Heart
7	Cholesterol
8	Feet
9	Stress
10	Preventing Complications
11	Diabetes Team
12	Living Well with Diabetes

Table 3: Patient questionnaires about nutrition, physical activity, social determinants of health and perception of benefit of RT-CGM

Nutrition	1. Starting the Conversation (STC) is an eight-item, simplified food frequency instrument[52] 2. 2. The National Center for Health Statistics[53] Six-item short form of the Food Security Survey
Physical Activity and Neighborhood Safety	1. The International Physical Activity Questionnaire (short) is a validated questionnaire that reviews the last 7 days of activity[54] 2. The *Neighborhood Questionnaire/Neighborhood Safety[55] is a* 16-item tool to assess sociability and an individual's satisfaction with the family's neighborhood. It has three subscales, and we will ask the Neighborhood Safety Subscale (items 1, 6, 10, 11, and 12) as a brief assessment of participants' ability to safely engage in physical activity in their neighborhoods 3. International Physical Activity Prevalence Study SELF-ADMINISTERED ENVIRONMENTAL MODULE(PANES)*:[56]* (Questions 2,4,6,9,13,14 and 16 of PANES with be assessed)

Behavioral Health	1. Depression symptoms will be assessed with the Patient Health Questionnaire 9 (PHQ-9)[57] 2. Diabetes distress will be assessed with The Problem Areas in Diabetes Scale 5 (PAID-5)[58] 3. Self-care and Self-efficacy activities will be assessed with the Summary of Diabetes Self-Care Activities (SDSCA0[59] 4. Self-Efficacy for Diabetes scale[60]
RT-CGM	1. Modified Harvard Joslin Diabetes Center CGM experiences, opinions, and expectations[61] 2. Perception of behavior change in nutrition and physical activity from RT-CGM use[51]
Family Member	1. Less than 13 years old habits questionnaire[62] 2. Greater than 13 years old starting the conversation and physical activity questionnaire. 3. Greater than 13 years old perception of CGM use by the family member and behavioral changes made as a result of the family member using CGM

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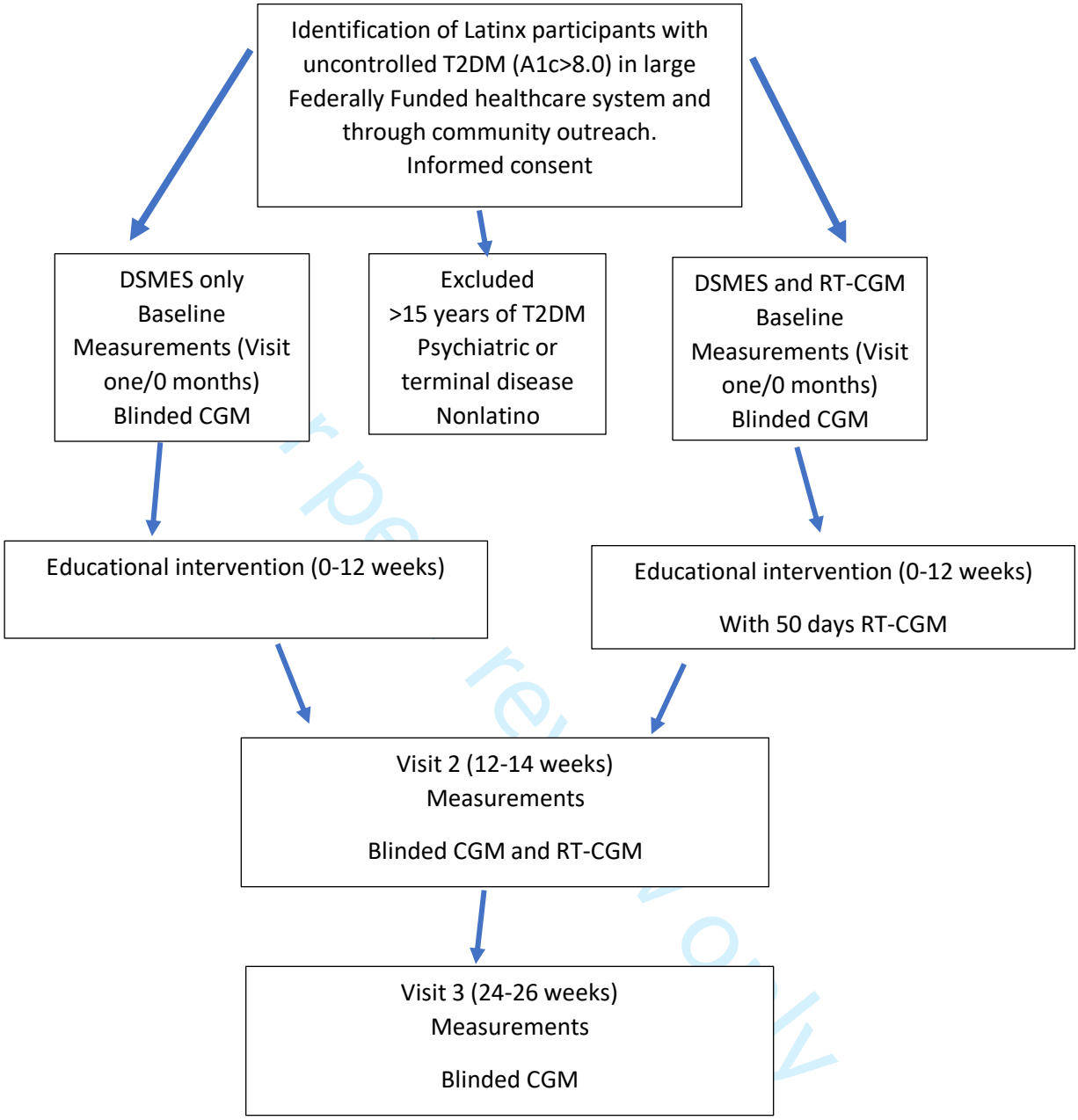
Figure Legend:
Figure 1- Flow chart
Figure 2- Data Collection Schematic


Identification of Latinx participants with uncontrolled T2DM (A1c>8.0) in large Federally Funded healthcare system and through community outreach.
Informed consent
DSMES only
Baseline Measurements (Visit one/0 months)
Blinded CGM
Excluded
>15 years of T2DM
Psychiatric or terminal disease
Nonlatino
DSMES and RT-CGM
Baseline Measurements (Visit one/0 months)
Blinded CGM
Educational intervention (0-12 weeks)
Educational intervention (0-12 weeks)
With 50 days RT-CGM
Visit 2 (12-14 weeks)
Measurements
Blinded CGM and RT-CGM
Visit 3 (24-26 weeks)
Measurements
Blinded CGM

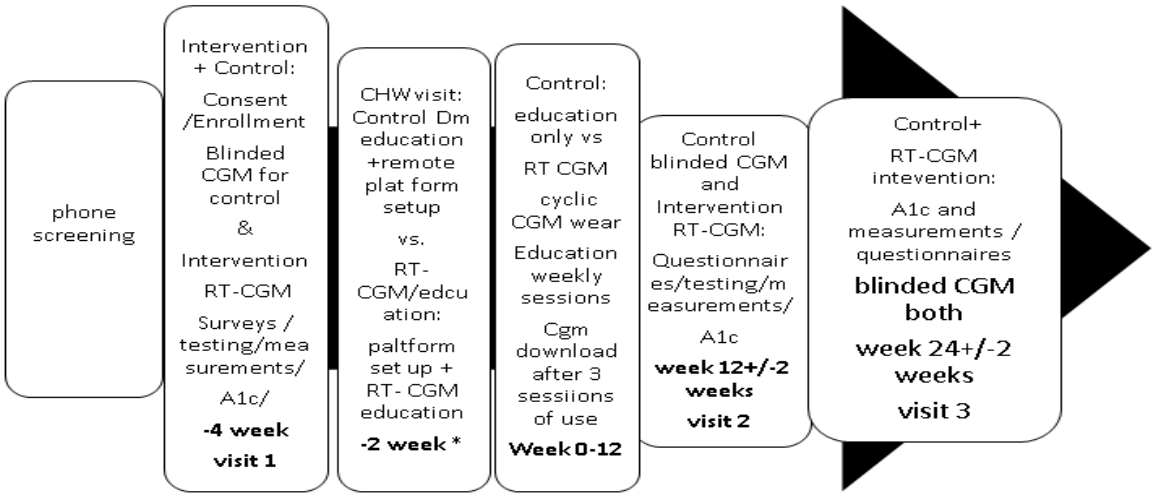


Figure 2: Schematic of Data Collection

IDENTIFICACIÓN: _____ Visita: _____ Fecha: _____

Cambios en el estilo de vida con el monitoreo continuo de glucosa (MCG) Diabetes

Para cada pregunta, marque la opción que mejor describa su experiencia con el Monitoreo Continuo de Glucosa (MCG).

1.Después de la monitorización continua de glucosa
Sientes que:

_ limitaste bebidas azucaradas
_ excluiste bebidas azucaradas
_ no hiciste cambios con respecto a bebidas azucaradas
_ nunca bebiste bebidas azucaradas antes del uso del MCG

2. Después del uso del Monitoreo Continuo de Glucosa:
Sientes que:

_ limitaste el arroz blanco
_ excluiste el arroz blanco
_ no hiciste cambios con el arroz blanco
_ nunca comiste arroz blanco antes del uso del MCG

3. Después del uso del Monitoreo Continuo de Glucosa:
Sientes que:

_ limitaste los cereales
_ excluiste los cereales
_ no hiciste cambios con los cereales
_ nunca comiste cereales antes del uso de MCG

4. Después del uso de Monitoreo Continuo de Glucosa:
Sientes que lees las etiquetas para el contenido de fibra:

_ si
_ no
_ leía las etiquetas para fibra antes del uso del MCG

5. ¿Hay algún alimento que limitó o excluyó después del uso continuo del monitor de glucosa? Enumere los tres principales o diga "ninguno".

_____

_____

_____

_____

6. ¿Piensa que el uso del Monitor Continuo de Glucosa lo hizo más propenso a ser más activo/a aumentar su ejercicio?

__ Si
__ No
__ Ya era muy activo/a
__ No se

7. ¿Era más probable que saliera a caminar o hiciera actividad física después de una comida si observaba un aumento de azúcar en la sangre en su Monitor Continuo de Glucosa?

__ Si
__ No
__ Ya salía a caminar o era activo después de las comidas
__No se

8- Piensa que está tomando su medicina mas regularmente como resultado de su participación en nuestras sesiones educacionales?

__Si

__No

__No lo sé

9. En general, ¿piensa que el Monitoreo Continuo de Glucosa contribuyó a cambios para lograr un estilo de vida "más saludable"?

__ Si
__ No
__ No Se

10. ¿Algo más que quieras contarnos sobre tu experiencia con el Monitoreo Continuo de Glucosa?

Monitoreo continuo de glucosa en tiempo real (RT-CGM) para diabetes

Paquete para participantes

¡Tome el control de su salud!

1. Dispositivo CGM de Dexcom:

El dispositivo de monitoreo continuo de glucosa (CGM) de Dexcom se inserta en la piel a nivel del estómago. Usted puede continuar con todas sus actividades diarias, incluso bañarse y nadar, mientras lo usa.

2. Comida:

En el registro proporcionado, registre cada comida y colación que coma, incluyendo la cantidad. Por ejemplo, si come pasta, registre “2 tazas de pasta” en lugar de solo “pasta”, o si comió queso, registre “3 oz de queso” en lugar de simplemente “queso”.

3- Actividad Física:

Registre la actividad física en el registro proporcionado. Por ejemplo, si va a caminar, registre: “20 minutos caminando a paso ligero” o si sube las escaleras, registre: “subí 3 pisos de escaleras”.

Monitoree su salud usando un CGM en Tiempo Real.

1.Si lo desea, continúe registrando cada comida y colación que come, incluyendo la cantidad.

2. Registre la actividad física.

3. Registre su nivel de glucosa antes de cada comida y, 1 y 2 horas después de cada comida o colación (observe el MGC para su nivel de glucosa en sangre en tiempo real).

Objetivos de glucosa en sangre
Glucosa antes de las comidas: 80 to 110 mg/dL 1 hora después de comer: menos de 160 mg/dL 2 horas después de comer: menos de 140 mg/dL

American Association of Clinical Endocrinologists, 2018

NO se desanime si sus valores son más altos al principio. Piense en lo que puede estar causando esos valores más altos. ¡Haz cambios para ver si puedes bajar esos números!

¡Con el sistema Dexcom RT-CGM podrá ver sus valores de glucosa en tiempo real!

Uso del sistema de monitorización continua de glucosa (CGM) de Dexcom:

1- Usted recibirá lecturas en la aplicación Dexcom G6 en su teléfono inteligente o en el receptor de Dexcom. Dexcom actualiza la lectura de glucosa cada cinco minutos.

2- Si la lectura en su dispositivo no coincide con cómo se siente, debe verificar su glucosa con su medidor.

3- Junto con el valor actual de su glucosa, Dexcom mostrará flechas de tendencia. Las flechas le indican si su nivel de glucosa es estable, si se dirige hacia arriba o hacia abajo y con qué rapidez.

¿Qué significan las flechas?	
	 La glucosa es estable. No cambia más de 1 mg/dL por minuto.
 La glucosa está cayendo lentamente. La glucosa podría disminuir de 30 a 60 mg/dL en los próximos 30 minutos.	 Glucosa está subiendo lentamente. La glucosa podría aumentar de 30 a 60 mg/dL en los próximos 30 minutos.
 La Glucosa está cayendo moderadamente La glucosa podría disminuir de 60 a 90 mg/dL en los próximos 30 minutos.	 Glucosa está subiendo moderadamente. La glucosa podría aumentar de 60 a 90 mg/dL en los próximos 30 minutos.
 La glucosa está cayendo rápidamente. La glucosa podría disminuir más de 90 mg/dL en los próximos 30 minutos.	 Glucosa está subiendo rápidamente. La glucosa podría aumentar más de 90 mg/dL en los próximos 30 minutos.

¿Qué cosas afectan la glucosa?

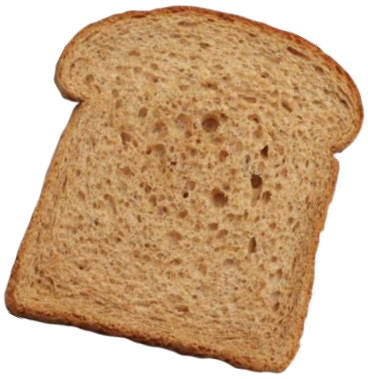
Muchas cosas pueden hacer que su nivel de glucosa suba o baje. Los alimentos pueden afectar su glucosa. Ciertos tipos de alimentos pueden elevar su nivel de glucosa más rápido y alto que otros.

Effect of FOOD on Glucose
↑ Carbohidratos
↑ Grasa
→ Proteína
↓ ↑ Alcohol

→ ningún efecto sobre la glucosa
↑ eleva la glucosa
↓ reduce la glucosa

Carbohidratos

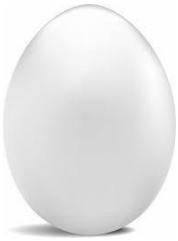
1. Los carbohidratos incluyen azúcares y almidones. Los azúcares se encuentran en alimentos como postres, frutas y algunos lácteos. Los almidones incluyen alimentos elaborados con granos (pan, cereal, arroz, etc.) y algunas verduras con almidón como guisantes, papas y frijoles. Los carbohidratos pueden incluirse en una dieta saludable. ¡Pero la CALIDAD y la CANTIDAD son importantes!



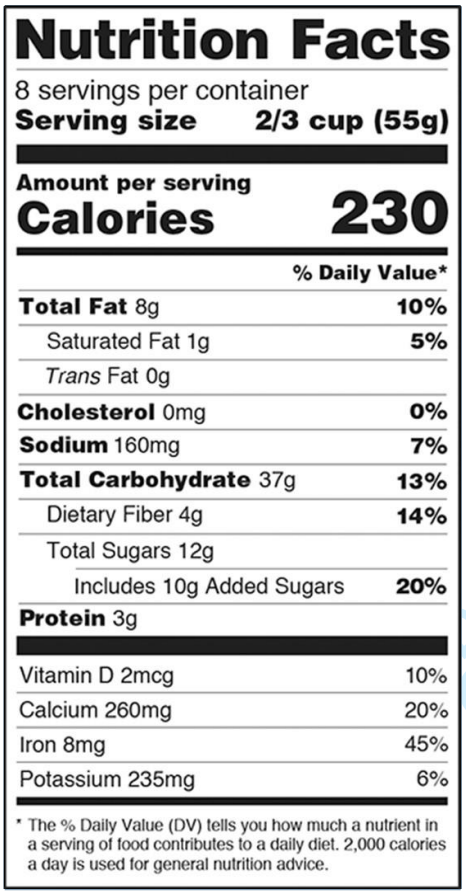
2. Los carbohidratos con fibra tienden a ser de mejor calidad que los que no tienen fibra. Revise las etiquetas de sus alimentos cuando elija sus carbohidratos y trate de comer alimentos con al menos 3 gramos de fibra por porción.

3. Observe su nivel de glucosa después de comer diferentes carbohidratos. Alrededor de dos horas después de una comida, observe que sucede con su glucosa. Por ejemplo, si come 1 taza de arroz y su glucosa sube mucho, considere disminuir a ½ taza o saltearse el arroz por completo. Tenga en cuenta la diferencia en su glucosa.

4. Trate de sustituir diferentes carbohidratos. Toma una tostada integral con 3 gramos de fibra, un vaso de leche descremada y un huevo duro (250-300 calorías). Compare su glucosa con los días cuando come un tazón de cereal y leche (250-300 calorías). Fíjate lo que hace que te sientas satisfecho por más tiempo.



Clave: Límite el tamaño de las porciones y elija alimentos con alto contenido de fibra.



Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Apunta a por lo menos 3 gramos de fibra. por ración y no más de 5 gramos de azúcar agregado.

Azúcar Agregado y Azúcar Natural

1- Como norma, evite los alimentos que tengan más de 5-10 gramos de azúcar agregado. Por ejemplo, el yogur saborizado puede tener entre 18 y 20 gramos de azúcar. Controle su glucosa después de comer su típico yogur en comparación con ½ taza de yogur griego natural con ¼ de taza de arándanos frescos u otra fruta fresca.

2- La fruta es saludable, pero contiene azúcar natural. Demasiada cantidad puede hacer que su glucosa se dispare. Una porción típica de fruta suele ser del tamaño de una pelota de tenis. Los ejemplos incluyen: 1 manzana pequeña, ½ plátano, 3/4 taza de bayas o 15 uvas. Observe su nivel de glucosa después de comer ½ taza de puré de manzana en comparación con una manzana pequeña.

Bebidas azucaradas:

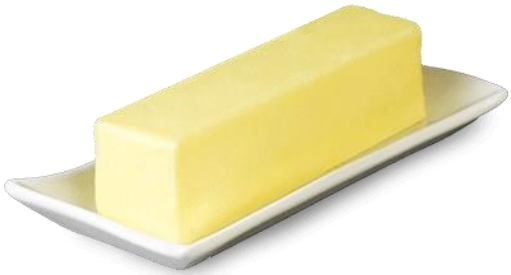
1. Nuestro cuerpo solo necesita agua, pero hemos entrenado nuestros cuerpos para anhelar el azúcar. Los jugos de frutas, las gaseosas, Gatorade®, las bebidas de café endulzadas están llenas de azúcar. ¡Si usted bebe estos, notará un aumento en su valor de glucosa en el RT-MGC!

2. Renunciar a las bebidas azucaradas puede ser un hábito difícil de cumplir, pero marcará una gran diferencia. Trate de sustituir las bebidas azucaradas con agua con limón u otros sabores sin calorías. Note la diferencia en su glucosa. Si sus bebidas son sin azúcar... ¡buen trabajo!

Clave: Evite los azúcares agregados y coma azúcar natural (como en la fruta) con moderación.

Grasa:

1. Gramo por gramo, la grasa contiene más calorías que otros nutrientes. Las grasas pueden estar “ocultas” en los alimentos que ya comemos. Por ejemplo, cuando usted bebe una taza de leche descremada en comparación con una taza de leche al 2%, usted bebe la misma cantidad, pero las calorías en la leche al 2% son bastante más altas. Una taza de porotos verdes con ajo y pimienta en comparación con mantequilla te da la misma cantidad de porotos verdes,



pero muchas más calorías cuando se agrega mantequilla. Eliminar un poco de grasa es una buena manera de reducir las calorías.

2. Si bien no hay "carbohidratos" en las grasas, comer demasiadas grasas puede provocar un aumento sostenido de la glucosa durante muchas horas. Esto se debe a que la grasa causa resistencia a la insulina (la propia insulina de su cuerpo no funciona tan bien). Observe su glucosa de 4 a 8 horas después de una comida rica en grasas. Considere elegir cortes de carne más magros y limitar algunos alimentos ricos en grasas, como la crema agria o la mayonesa.

3. Incluso las “grasas buenas”, como las nueces, pueden aumentar su glucosa, lo que resalta la necesidad de porciones pequeñas, como no más de 15 a 18 nueces por porción. Las grasas no saturadas son mejor opción que las saturadas, pero aún debe prestar atención a la cantidad.

Clave: Recuerde que la grasa es la más alta en calorías. Disminuya sus calorías totales eliminando algunas grasas o cambiando a opciones bajas en grasas.

Alcohol:

Lamentablemente, el alcohol es otra “caloría vacía”. Controle sus niveles de azúcar en la sangre después de una bebida mezclada o una cerveza. Limite el alcohol tanto como sea posible.

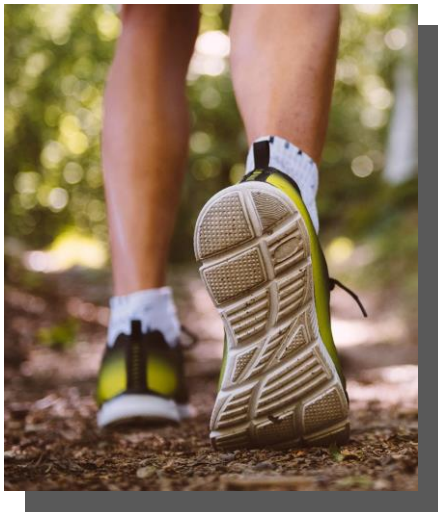
Clave: ¡No beba sus calorías!

Actividad física:

Efecto de la ACTIVIDAD sobre la Glucosa	
→ ↓	Ejercicio de baja intensidad
↑ ↓	Ejercicio de intensidad moderada
↑ ↓	Ejercicio de alta intensidad

1. La actividad física tiene muchos beneficios, incluyendo la pérdida de peso, la reducción de la presión arterial y la mejora del colesterol. Además, la actividad de ligera a moderada, como caminar, puede reducir la glucosa. Apunta a tus 30 minutos al día de actividad de intensidad moderada y luego aumenta con el tiempo. Intensidad moderada significa que su corazón está latiendo un poco más rápido y está respirando un poco más fuerte (sin estar con tanta falta de aire).

2. Considere agregar 10 minutos de caminar o subir las escaleras después de cada comida además de su ejercicio planificado. Utilice su consumo de alimentos como un disparador; después de cada comida, salga a caminar y vea cómo afecta su glucosa.



3. La actividad de moderada a intensa, como el levantamiento de pesas, el entrenamiento en intervalos o las carreras de velocidad, puede aumentar inicialmente el nivel de azúcar en la sangre, pero luego mejorar el nivel de azúcar en la sangre a lo largo del día.

4. Agregue más caminatas a sus actividades diarias. Camine como parte de su viaje. Elija un lugar más alejado en el estacionamiento. En lugar de tomar el transbordador, camine. Vaya por las escaleras. ¡Agregar pasos a su rutina diaria es una excelente manera de aumentar la actividad física y aliviar el estrés!

5. Esté preparado para enfrentar los obstáculos ¿Qué harás si hay mal tiempo? ¿Qué harás si se vuelve aburrido? Si tiene un plan para abordar estas situaciones, es más probable que se mantenga encaminado.
6. Compare su nivel de glucosa en los días en que es más activo frente a los días en que es menos activo.

Clave: La actividad física puede reducir la glucosa, entre otras cosas. Trabajar más "pasos" en su día es una excelente manera de aumentar su nivel de actividad física y todos los beneficios que conlleva.

Glucosa Sanguínea Baja:

1- Si usa insulina o una pastilla que hace que su cuerpo libere más insulina, puede correr el riesgo de tener un nivel bajo de glucosa sanguínea. Cuando pierde peso o elige alimentos más saludables, es posible que necesite menos medicamento(s) para la diabetes.

2- Los síntomas de glucosa baja incluyen temblores, sudar, confusión, sensación de debilidad y posiblemente hambre. Si siente estos u otros síntomas inusuales, verifique con una prueba de punción del dedo en su medidor de glucosa.

3- Para tratar la glucosa baja, debe comer/beber algo con aproximadamente 15 gramos de carbohidratos/azúcar. Esto podría incluir ½ taza de jugo, una taza de lecha descremada, o 3 a 4 tabletas de glucosa. Tomará al menos 15 minutos para que estos azucares tengan efecto. Si su glucosa sigue siendo inferior a 70 mg/dL después de 15 minutos, trate con otros 15 gramos de azúcar.

4- Si tiene lecturas inferiores a 70 mg/dL, debe hablar con su médico. Pregunte si debe reducir las dosis de sus medicamento(s) para evitar niveles bajos de glucosa.

MCG en tiempo real (RT-CGM) Dexcom

Sus metas para los 3 meses: ¡Mejore sus niveles de glucosa y aprenda qué le hacen a su glucosa los alimentos y la actividad!

1. Revise los siguientes valores en su aplicación Clarity para cada sesión de 10 días:

- Promedio de glucosa antes de las comidas
- Promedio de glucosa después de las comidas
- Glucosa promedio durante el período total de uso

2. Identificar los factores que resultaron en los mejores y peores valores de glucosa.

3. Elija alimentos y actividades que mejoren su nivel de glucosa antes y después de las comidas. Continúe registrando su comida, actividad, los valores de glucosa antes y después de las comidas en el registro.

¡Estar saludable o en forma no es una tendencia o una moda pasajera, es un estilo de vida!

The people depicted are not patients and were taken with the participants knowledge.

Real-Time Continuous Glucose Monitoring (RT-CGM) for Diabetes

Participant Packet

Take Charge of Your Health!

1. CGM Device:

The Continuous Glucose Monitoring (CGM) device is inserted in the skin of your stomach, arm or upper buttock. You can continue all your daily activities, including showering and swimming, while you wear it.

2. Food:

In the log provided, record each meal and snack you eat, including the amount. For example if you eat pasta record “2 cups of pasta” rather than just “pasta” or if you have cheese record “3 oz of cheese” rather than just “cheese”.

3. Physical Activity:

Record physical activity in the log. For example if you go for a walk, record “20 minutes brisk walking” or if you take the stairs, log: “climbed 3 flights of stairs”.

Monitor your Health Using CGM Real-Time (RT-CGM)

1. Continue to record each meal and snack you eat, including the amount.

2. Record physical activity.

3. Record your glucose before each meal and 1 and 2 hours after each meal or snack (look at CGM for your real time blood glucose).

Blood Glucose Goals
Pre-meal glucose: 80 to 110 mg/dL
1 hour after eating: less than 160 mg/dL
2 hours after eating: less than 140 mg/dL

American Association of Clinical Endocrinologists, 2018

DON'T get discouraged if your values are higher at first. Think about what may be causing those higher values. Make changes to see if you can get those numbers down!

With RT-CGM you will be able to see your glucose values in real time with the Dexcom system!

Using the Dexcom Continuous Glucose Monitoring (CGM) system:

1. You will receive readings on the Dexcom G6 app on your Smartphone or the Dexcom receiver. The Dexcom updates the glucose reading every five minutes.

2. If the reading on your device does not match how you feel, you should check your glucose with your meter.

3. Along with the current value of your glucose, the Dexcom will show trend arrows. Arrows tell you if your glucose is stable, heading up, or down and how quickly.

What do the arrows mean?	
	Glucose is stable. It is not changing more than 1 mg/dL per minute.
Glucose falling slowly. Glucose could decrease 30 to 60 mg/dL in the next 30 minutes.	Glucose rising slowly. Glucose could increase 30 to 60 mg/dL in the next 30 minutes.
Glucose falling moderately. Glucose could decrease 60 to 90 mg/dL in the next 30 minutes.	Glucose rising moderately. Glucose could increase 60 to 90 mg/dL in the next 30 minutes.
Glucose falling quickly. Glucose could decrease more than 90 mg/dL in the next 30 minutes.	Glucose rising quickly. Glucose could increase more than 90 mg/dL in the next 30 minutes.

What Things Affect Glucose?

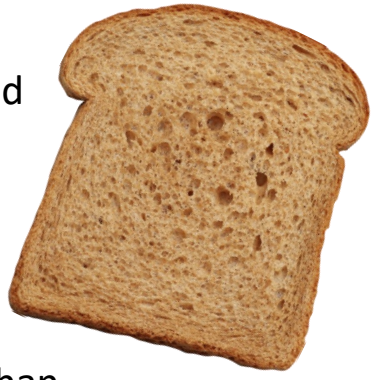
Effect of FOOD on Glucose	
↑	Carbohydrates
↑	Fat
→	Protein
↓ ↑	Alcohol

→ no effect on glucose
↑ raises glucose
↓ lowers glucose

Many things can make your glucose go up or down. Food can affect your glucose. Certain types of food may raise your glucose faster and higher than others.

Carbohydrates

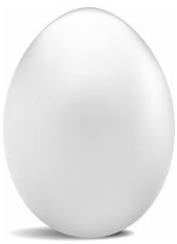
1. Carbohydrates include sugars and starches. Sugars are found in foods such as desserts, fruit and some dairy. Starches include foods made from grains (bread, cereal, rice, etc.) and some starchy vegetables like peas, potatoes, and beans. Carbohydrates may be included in a healthy diet. But QUALITY and QUANTITY are important!



2. Carbohydrates with fiber tend to be better quality than those without fiber. Check your food labels when you are choosing your carbs and aim to eat foods with at least 3 grams of fiber per serving.

3. Notice your glucose level after eating different carbohydrates. About two hours after a meal, notice what happens to your glucose. For example if you have 1 cup of rice, and your glucose goes up a lot, consider decreasing to ½ cup or skipping rice altogether. Note the difference in your glucose.

4. Try substituting different carbohydrates. Have a piece of whole wheat toast with 3 grams of fiber, a glass of skim milk, and one hard-boiled egg (250-300 calories). Compare your glucose to when you eat a bowl of cereal and milk (250-300 calories). Observe what keeps you feeling full longer.



Key: Limit portion sizes and choose foods with high fiber.

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Aim for <u>at least</u> 3 grams of fiber per serving and <u>no more than</u> 5 grams of added sugar.

Added Sugar and Natural Sugar:

1. As a rule, avoid foods that have more than 5-10 grams of *added* sugar.

   For example, flavored yogurt may have as much as 18-20 grams of sugar. Watch your glucose after eating your typical yogurt vs. ½ cup plain Greek yogurt with ¼ cup fresh blueberries or other fresh fruit.

2. Fruit is healthy but is still has natural sugar in it. Too much can cause your glucose to spike. A serving of fruit is typically about the size of a tennis ball. Examples include: 1 small apple, ½ of a banana, 3/4 cup of berries or about 15 grapes. Observe your glucose after eating ½ cup applesauce vs. a small apple.

Sugared Beverages:

1. Our body only needs water but we have trained our bodies to crave this sugar. Fruit juice, sodas, Gatorade®, sweetened coffee drinks all are filled with sugar. If you drink these you will notice a spike in your glucose value on the RT-CGM!

2. Giving up sugary drinks can be a hard habit to break but will make a huge difference. Try to substitute water with lemon or other non-calorie flavors for these sugared beverages. Notice the difference in your glucose. If your beverages are already sugar free… great job!

Key: Avoid added sugars and eat natural sugar (like in fruit) in moderation.

Fat:

1. Gram for gram, fat contains more calories than other nutrients. Fats may be "hidden" in foods we already eat. For example, when your drink a cup of skim milk vs. a cup of 2% milk, you drink the same amount, but calories in the 2% milk are quite a bit higher. One cup of green beans with garlic pepper, versus butter gives you the same amount of green beans, but a lot more calories when butter is added. Cutting out some fat is a good way to reduce calories.
2. While there are no "carbohydrates" in fat, eating too much fat may cause a sustained rise in glucose over many hours. This is because fat causes *insulin resistance* (your body's own insulin does not work as well). Observe your glucose 4 to 8 hours after a high-fat meal. Consider choosing leaner cuts of meat, and limiting some high-fat foods such as sour cream or mayonnaise.

3. Even "good fats" such as nuts can increase your glucose which highlights the need for small portion sizes such as no more than 15-18 nuts per serving/sitting. Unsaturated fats are a better choice than saturated, but you still need to pay attention to the quantity.

Key: Remember that fat is highest in calories. Decrease your total calories by cutting out some fats or switching to lower-fat options.

Alcohol:

Unfortunately alcohol is another "empty calorie". Watch your blood sugars after a mixed drink or beer. Limit alcohol as much as possible.

Key: Don't drink your calories!

Physical Activity:

Effect of ACTIVITY on Glucose	
→ ↓	Light-intensity exercise
↑ ↓	Moderate-intensity exercise
↑ ↓	High-intensity exercise

1. Physical activity has many benefits, including weight loss, lowering blood pressure, and improving cholesterol. In addition, light to moderate activity such as walking can lower glucose. Aim for your 30 minutes a day of moderate-intensity activity and then increase over time. Moderate intensity means your heart is beating a little faster and you are breathing a little harder (without being too out of breath).

2. Consider adding 10 minutes of walking or taking the stairs after each meal in addition to your planned exercise. Use your food intake as a trigger; after each meal, go for a walk and see how it affects your glucose.

3. Moderate to intense activity such as weight lifting, interval training or sprinting may initially increase your blood sugar but then improve your blood sugar over the course of the day.

4. Add more walking into your daily activities. Walk as part of your commute. Choose a farther spot in the parking lot. Walk instead of taking the shuttle. Take the stairs. Adding steps to your daily routine is a great way to increase physical activity and relieve stress!

5. Be prepared to address the barriers. What will you do if the weather is bad? What will you do if it gets boring? If you have a plan to address these situations, you are more likely to stay on track.

6. Compare your glucose level on days you are more active vs. days you are less active.

Key: Physical activity can lower glucose, among other things. Working more "steps" into your day is a great way to increase your physical activity level and all the benefits that go with it.

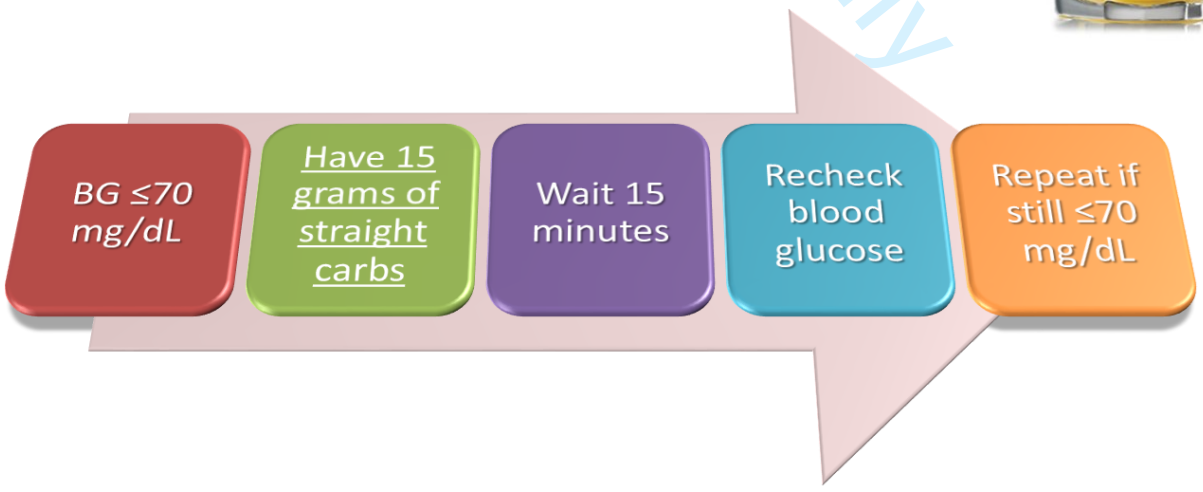
Low Blood Glucose:

1. If you take insulin, or a pill that makes your body release more insulin, you may be at risk for low blood glucose. When you lose weight or make healthier food choices, you may need less of your diabetes medication(s).

2. Symptoms of low glucose include shakiness, sweating, confusion, feeling weak and possibly hungry. If you feel these or any other unusual symptoms, check your CGM glucose reading. You may also want to confirm with a fingerstick test on your glucose meter.

3. To treat low glucose, you should eat/drink something with about 15 grams of carbohydrates/sugar. This might include ½ cup of juice, one cup of skim milk, or 3 to 4 glucose tablets. It will take at least 15 minutes for these sugars to work. If your glucose is still less than 70 mg/dL after 15 minutes, treat with another 15 grams of sugar.

4. If you have any readings less than 70 mg/dL, you should talk with your provider. Ask if you should reduce your medication(s) doses to prevent low glucose.



Dexcom CGM Real-Time (RT-CGM)

Your goals for the 3 months: Improve your glucose numbers and learn what food and activity does to your glucose!

1. Review at the following values on your Clarity App :
   - Pre-meal glucose average
   - Post-meal glucose average
   - Average Glucose f
2. Identify factors that resulted in the best and the worst glucose values.
3. Choose foods and activities that will improve your pre and post-meal glucose. Continue to record your food and activity, and pre and post meal glucose values on the log.

The people depicted are not patients and were taken with the participants knowledge.

UNIVERSIDAD DE WASHINGTON
FORMULARIO DE CONSENTIMIENTO
Compañeros en Salud y Monitorización Continua de Glucosa en Tiempo REAL

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Preguntas sobre el estudio: Evelin Jones, Coordinadora de investigación
Número telefónico: 206-221-9369

Declaración del investigador

Lo invitamos a participar en nuestra investigación. El propósito de este formulario de consentimiento es brindarle la información necesaria para ayudarle a decidir si desea participar en nuestro estudio. Favor de leer el formulario completo. Lo invitamos a hacer cualquier pregunta sobre nuestra investigación. Esperamos que al contestar todas sus preguntas, usted pueda decidir si desea participar en el estudio o no, ya que su participación en el estudio seria completamente voluntaria. Le daremos una copia de este formulario para sus registros. Este proceso se llama "consentimiento informado".

INFORMACIÓN IMPORTANTE DEL ESTUDIO

El estudio "Compañeros en Salud" con monitoreo continuo de glucosa comparará cómo funciona un programa de educación sobre la diabetes apropiado a la cultura Latina, en inglés y español, con y sin un dispositivo de monitoreo continuo de glucosa (azúcar) (CGM).

¿POR QUÉ ESTAMOS HACIENDO ESTE ESTUDIO Y QUÉ SE LE PEDIRÁ HACER SI PARTICIPA?

Al realizar este estudio, esperamos aprender si la intervención educativa ayuda a mejorar el cuidado de la Diabetes. Al mismo tiempo, estamos interesados en aprender si el monitoreo continuo de azúcar, y la intervención educativa juntas pueden tener mejores resultados en el control de la diabetes. Usted recibirá educación sobre la diabetes y puede ser asignado a un grupo el cual tendrá el dispositivo de monitoreo de los niveles de azúcar en sangre en tiempo real (RT). El segundo grupo también recibirá el programa de educación, pero puede que no reciba el dispositivo para monitorear los niveles de azúcar en tiempo real.

¿Cuál serían algunas razones para no PARTICIPAR EN ESTE ESTUDIO?

Se le pediría atender clases para aprender sobre el manejo y control de la diabetes. Es posible que prefiera simplemente continuar trabajando con su médico de cabecera en controlar su diabetes y no recibir educación sobre diabetes. También es posible que no esté interesado/a en recibir el dispositivo de monitoreo continuo de glucosa. Se le asignará

aleatoriamente para utilizar o no un CGM en tiempo real. Esto será decidido al azar, no por usted ni por el equipo de estudio.

¿CUALES SON ALGUNAS RAZONES PARA PARTICIPAR EN ESTE ESTUDIO?

La educación sobre la diabetes puede ayudar a mejorar su diabetes y ayudarle a vivir una vida saludable. Además, el dispositivo de monitoreo continuo de glucosa (CGM) puede ayudarle a mejorar el control de diabetes aún más de lo que ya lo está haciendo.

¿TIENE QUE PARTICIPAR EN EL ESTUDIO?

No, no tiene que participar en el estudio. Si decide participar en el estudio, debe ser porque realmente desea ser voluntario. Si decide no hacerlo, no perderá ningún servicio, beneficio o derecho que ya tiene y seguirá recibiendo tratamiento para su diabetes. También es importante que usted sepa que puede retirarse en cualquier momento durante el estudio.

¿Y SI QUIERE MÁS INFORMACIÓN?

El resto de este documento le brinda más información sobre el estudio, incluyendo:

- Qué se hará en las visitas de investigación
- Los riesgos del estudio
- Quién pagará el tratamiento si se lesiona por los procedimientos del estudio
- Cómo protegeremos su privacidad
- Con quién hablar si tiene problemas, sugerencias o inquietudes

PROPÓSITO DEL ESTUDIO

Este estudio proporcionará un programa de educación sobre diabetes apropiado a la cultura Latina, en inglés y español. Algunos participantes usarán un monitor continuo de glucosa (CGM). Queremos saber si la educación sobre la diabetes ayuda a reducir los niveles de azúcar, y si el monitoreo continuo de glucosa lo hace aún más útil.

PROCEDIMIENTOS DE ESTUDIO

El estudio se llevará a cabo a través de clínicas de salud de Sea Mar, clínicas de la Universidad de Washington y de la comunidad. El estudio incluirá a 100 personas con diabetes tipo 2.

Puede negarse a responder cualquier pregunta, prueba, inventario, cuestionario o entrevista.

Se le asignará aleatoriamente a **uno de dos grupos:**

1. Este grupo recibirá educación sobre diabetes de Compañeros en Salud sin el monitoreo continuo de la glucosa (CGM).

- Se le pedirá que use un CGM que esté **cegado:** Esto significa que no le mostrará sus números de azúcar en la sangre hasta el final del estudio.
- Usted continuará analizando su nivel de azúcar en la sangre usando su medidor de glucosa como lo recomiende su doctor de cabecera.

2. Este grupo recibirá educación sobre diabetes de Compañeros en Salud con el monitoreo continuo de la glucosa (CGM).

- Se le pedirá que use un CGM que no esté **cegado:** Esto significa que le mostrará sus números de azúcar en la sangre en tiempo real (RT), a medida que están sucediendo.
- El grupo en el que se encuentra se decide al azar (como lanzar una moneda al aire). Tiene las mismas posibilidades de estar en cualquiera de los dos grupos.

¿Qué es un dispositivo de monitoreo continuo de la glucosa (CGM)?

El monitoreo continuo de glucosa (CGM) es una forma de medir el nivel de azúcar o glucosa en la sangre. El dispositivo funciona de la siguiente manera: Guarda los números de azúcar en la sangre para que pueda verlos todo el tiempo (en tiempo real) o puede verlos más tarde. El dispositivo (CGM) tiene un filamento delgado y flexible que se inserta debajo de la piel y solo requiere un pinchazo en la piel. Los lugares del cuerpo donde se puede poner el dispositivo son los siguientes: puede usarlo en el estómago, brazo o gluteo. Una vez que está colocado, el dispositivo puede permanecer allí por 10 días. Un transmisor pequeño es usado sobre la piel donde está colocado el dispositivo para registrar los valores de azúcar. El dispositivo entero es aproximadamente del tamaño de una pequeña galleta. El transmisor envía los resultados de glucosa de forma electrónica a un teléfono inteligente o a un dispositivo donde podrá verlos inmediatamente, o más tarde.

También puede utilizar una aplicación de teléfono celular llamada Dexcom Clarity. Esta aplicación puede compartir sus números de azúcar en la sangre con el equipo de investigación. También puede optar por compartir estos números con un miembro de su familia, pero solo si usted lo desea. Para compartir los niveles de azúcar en la sangre, su familiar también deberá usar la aplicación y tener su permiso para ver sus niveles de azúcar.

Le daremos todos los materiales que necesitará. Tendrá un sobre con franqueo pre pago para devolver el dispositivo por correo al final de los 10 días. Si no puede enviarlo por correo, un Navegador del Paciente (Patient Navigator), anteriormente conocido como trabajador de salud comunitario (CHW) o educador de salud (HE) puede ir a su casa para recogerlo o puede llevarlo a la clínica.

A veces, un CGM puede caerse accidentalmente o dejar de funcionar antes del final de los 10 días. Si esto sucede dentro de los primeros 3 días, le daremos un nuevo CGM.

¿Cuánto tiempo dura el estudio y qué debo hacer?

Su participación en el estudio será por 6 meses **con las siguientes visitas:**

- 3 visitas de investigación programadas (1-1.5 horas cada una),
- 1 visita con el navegador del paciente o educadores de salud para enseñanza (1-1.5 horas), que podría ser junto con la primera visita del estudio,
- 12 clases de diabetes (1-1.5 horas cada una, ofrecidas en diferentes momentos en inglés y español) con un tiempo total de participación en el estudio de aproximadamente 25 horas.

Si desea participar en este estudio, le pediremos que lea y firme este documento de consentimiento antes de darnos algún dato. Las visitas de investigación se llevarán a cabo a través de telemedicina en su hogar o, si lo prefiere, en una Clínica local de Sea Mar o de la Universidad de Washington. Puede optar por hacer parte de las visitas en su casa y parte en una clínica.

Si firma este formulario en línea, se le enviará por correo electrónico una copia del formulario de consentimiento a una dirección de correo electrónico que proporcione. Será un documento "PDF". La mayoría de las computadoras ya tienen instalado el software de PDF, que le permitirá abrir, leer o imprimir el formulario de consentimiento. El correo electrónico que le enviemos incluirá un enlace al software de PDF (como Adobe Acrobat Reader) en caso de que su computadora aún no lo tenga. Sin costo alguno usted puede recibir una copia impresa del formulario de consentimiento. Si desea retirar su consentimiento, comuníquese con el coordinador de la investigación en la página 1 de este formulario de consentimiento.

También le pediremos que proporcione información de un contacto (número de teléfono, dirección, correo electrónico e información de contacto de familiares y / o amigos). Nosotros solo utilizaremos esta información para contactarlo acerca de las clases, las visitas, y para obtener los datos dados por el dispositivo que mide sus niveles de glucosa.

Después de firmar este consentimiento informado, le mediremos su hemoglobina A1C por medio de una punción en un dedo. Este análisis de sangre nos da un promedio de su nivel de azúcar en la sangre de los últimos 2-3 meses. Si usted es mujer, también le pediremos una prueba de embarazo en orina, ya que nuestro estudio no incluirá a mujeres embarazadas. Si la visita inicial no es en persona, es posible que le pidamos que vaya al laboratorio para una muestra de sangre y una prueba de orina. No puede participar en el estudio si su A1C es inferior a 8.0 o si está embarazada. Si durante el periodo del estudio usted llegase a quedar embarazada, usted continuará su diabetes y atención del embarazo con su proveedor de atención médica, y no continuará en el estudio.

1. <u>Visita 1: Detección y recopilación de datos</u>

- Se lleva a cabo 2-4 semanas antes de la primera clase de diabetes
- Tardará de 1 a 1,5 horas en completarse
- Mediremos su altura, peso, presión arterial y circunferencia de la cintura (usando una cinta métrica alrededor de su cintura).
- Le haremos preguntas sobre su diabetes, su salud y sus hábitos.
- Le asignaremos aleatoriamente a las clases de diabetes <u>con o sin</u> CGM.
- Le diremos las fechas de las 12 clases semanales (en español o inglés).

- Le pediremos que use un app en su teléfono para contar sus pasos y así medir cuanto camina, Si no tiene un app en su teléfono, le daremos un dispositivo llamado podómetro y le mostraremos cómo usarlo. Le pediremos que use el podómetro o mantenga su teléfono con usted mientras está despierto tanto como sea posible durante el estudio.
- Le daremos una tarjeta de regalo de $ 50.00 al final de la visita.

2. <u>Visita de seguimiento con un Navegador del Paciente (PN) , un educador de salud (HE) o personal del estudio.</u>

El mismo día de la primera visita del estudio o en otro momento, en su casa o en la clínica local, antes de comenzar las clases de diabetes, un Navegador del Paciente (PN) o educador de salud (HE) o personal del estudio, lo visitará o usted puede ir a verlo en una clínica local para que:

Le ayuden con Zoom y acceso a Internet. Si usted no tiene acceso a internet en su casa, le proveeremos con un dispositivo con acceso a internet para que use durante las 12 clases. También le mostrarán cómo insertar el CGM. Le ayudarán a resolver problemas comunes que las personas a veces tienen al usar los CGM.

Si está en el grupo de tiempo real (RT-CGM), el Navegador del Paciente/ HE lo ayudará a instalar la aplicación Clarity en su teléfono que necesitará para usar el dispositivo. Le mostrarán cómo compartirlo con los miembros de la familia si así lo desea. El Navegador del Paciente / HE también hablará con usted sobre cómo los alimentos y la actividad física afectan su nivel de azúcar en la sangre. Le enseñarán cómo usar el CGM para ver sus niveles de azúcar en la sangre y lo ayudarán a comprender lo que significan los números.

El Navegador del Paciente /HE le dará un registro de alimentos y actividades. Si elige una visita de telemedicina / Zoom, el Navegador del Paciente /HE puede preguntarle si puede verlo en persona para hacer mediciones (A1C y mediciones corporales).

Después de la visita 1, todos los participantes en ambos grupos usarán un CGM ciego durante 10 días. Esto significa que no verá sus números de azúcar en la sangre. Luego devolverá el CGM en la primera clase de diabetes en persona, o puede enviarlo por correo.

Si no obtiene un CGM, continuará controlando sus valores de azúcar según lo recomendado por su médico mediante una punción en el dedo.

3. <u>Clases de Educación: Clases compañeros en salud</u>

A continuación, asistirá a clases semanales de educación sobre la diabetes durante 12 semanas.

Estas serán clases grupales una vez a la semana a través de tele salud / Zoom o en un aula de Sea Mar. Usted estará en la clase con otras personas que tienen diabetes tipo 2. Le pediremos que asista a las 12 clases. Cada clase durará 1-1.5 horas. Le daremos todos los materiales para cada clase.

Estas clases utilizarán la plataforma Zoom. Las clases se grabarán para que pueda verlas más tarde. Antes de unirse a cada clase, verá un mensaje que dice que la sesión será grabada. Además, aunque le animamos a que aparezca en cámara durante las clases, no tiene que hacerlo. Puede elegir mostrar u ocultar su cámara.

Al final de la primera clase, las personas que estén en el grupo de monitoreado en tiempo real (RT-CGM), recibirán 15-30 minutos de educación sobre comida y actividades y como ver lo que está pasando con su azúcar en el CGM. Les mostraremos como empezar a usar el dispositivo CGM al final de esta clase, los Navegadores del Paciente / HE o personal del estudio quizá lo contacten al día siguiente para asegurarse de que no esté teniendo ningún problema usando el dispositivo.

4. Visita de estudio 2

Al final de las 12 clases, haremos lo siguiente:

- Le haremos preguntas sobre su diabetes
- Mediremos una A1C para ver cómo han sido sus niveles de azúcar en la sangre
- Haremos las mismas mediciones corporales que hicimos en su primera visita.
- Le entregaremos una tarjeta de regalo de $ 50.00 al final de la visita.

- Si no está en el grupo de CGM en tiempo real (RT-CGM):
  - Usted usará un CGM ciego una vez más durante 10 días, empezando 3 dias antes de la clase 11, el cual va a devolver después de 10 días. Si se olvida, lo puede empezar a usar lo antes posible.
  - El Navegador del Paciente /HE o el personal del estudio de investigación lo ayudarán a insertar el CGM ciego a través de telemedicina o en persona si es necesario.
  - Usted no verá sus niveles de azúcar en la sangre

- Si está en el grupo CGM en tiempo real (RT-CGM):
  - Usará el RT-CGM una vez más durante 10 días, comenzando 3 días antes de la clase 11. Si se olvida, lo puede empezar a usar lo antes posible.
  - Podrá ver sus niveles de azúcar en la sangre a medida que ocurren.

Después de la visita número dos, continuará trabajando en su diabetes con su médico de atención primaria. Las clases de diabetes y el uso de RT-CGM habrán terminado. Debe preguntarle a su médico si tiene alguna pregunta sobre su diabetes.

5. Visita de estudio 3

Esta visita será 3 meses después de la última clase de diabetes.

Pediremos a todos los participantes que usen un sensor cegado durante 10 días. Esta será la última vez que lo usarán. Le haremos las mismas preguntas que le hicimos en sus otras visitas. También mediremos la A1C y las medidas corporales.

¿Cuándo usa el RT-CGM?

Si está en el grupo de dispositivos de monitoreo continuo de glucosa en tiempo real (RT-CGM), después de su primera clase de diabetes, comenzará a usar el dispositivo durante un total de cinco ciclos de 10 días de uso. Recibirá 2 sensores adicionales en caso de que el CGM se caiga o se salga antes.

- Comience a usar el RT-CGM una vez que complete su primera clase de diabetes. Usar durante 10 días.
- Luego deje de lado durante 7 días
- Luego vuelva a usarlo durante 10 días
- El ciclo de uso es durante 10 días, luego descanso durante 7 días y luego de uso durante 10 días hasta que haya completado un total de 50 días (5 sesiones) de uso del sensor.
- El objetivo es iniciar el último sensor 3 días antes de la clase educativa número 11 y usarlo por 10 días.

Esta tabla muestra el programa de visitas, la información que se recopilará y el programa de uso de CGM para cada grupo.

Tipo de Visita	Detección y Visita 1 (Primera Visita)	Visita 2	Visita 3
Semana de estudio	Semana Cero	Semana 12*	Semana 24*
Lea y firme el consentimiento informado	X		
Contacto de emergencia	X		
Prueba de embarazo en orina (Mujeres)	X		
Datos demográficos	X	X	X
Medicamentos, historial médico	X	X	X
Cuestionarios	X	X	X
Análisis (Prueba) de sangre por punción digital HbA1C	X	X	X
Presión arterial, pulso, altura (estatura), peso, medidas de cintura	X	X	X
Podómetro durante 10 días	X	X	X
Visita del navegador del paciente	X		
Asignación aleatoria al grupo CGM	X		
Grupo CGM cegado	CGM Cegado 10 días	CGM Cegado 10 días	CGM Cegado 10 días
Grupo RT-CG	CGM Cegado 10 días	**RT-CGM** (cinco ciclos durante 10 días, siete días de descanso)	CGM Cegado 10 días
12 semanas de clases de diabetes		X	X
Encuesta a miembros de la familia (ambos grupos)	X	X	

Tarjeta de regalo de $50	**X**	**X**	**X**

* dentro de 2 semanas de esta fecha.

Despues de completar el estudio, al final de la visita 3, le ofreceremos a los participantes del grupo control/ciego que expresen interés, la posibilidad de usar 3 sensores Dexcom en Tiempo Real mientras tengamos suficientes suministros. No tendrá que pagar por estos sensores. Los datos recolectados por estos dispositivos no se utilizarán en el estudio, y el equipo del estudio no tendrá acceso a estos datos.

Si recibe estos 3 sensores, será responsable de informar todos los valores de glucosa recopilados por estos dispositivos a su equipo clínico de Seamar, y deberá comunicarse con este equipo si tiene problemas o preguntas sobre el uso de los sensores.

RESPONSABILIDADES

Clases de Compañeros en Salud (Ambos Grupos)
Es importante que complete todas las visitas del estudio, los procedimientos y las clases para ayudarnos a saber qué tan útil será el programa de educación sobre la diabetes.

CGM Cegado: Todos los participantes en ambos grupos usarán un dispositivo CGM cegado 10 días antes de la primera clase de diabetes, después del final de la última clase y nuevamente 3 meses después.

Clases de Compañeros en Salud con RT-CGM
Si está en el grupo de CGM en tiempo real, es importante que use el RT-CGM en los momentos programados para que podamos aprender qué tan útil es el CGM. Le pediremos que use el CGM durante 10 días, en 5 sesiones durante 12 semanas. Si no puede usar el CGM, comuníquese con el personal del estudio.

Participación de los miembros del hogar:
Si tiene hijos mayores de 8 años, cónyuge/pareja u otros miembros del hogar:

- Preguntaremos si estarían dispuestos a completar un cuestionario de menos de 10 minutos sobre sus hábitos alimenticios y actividad.
- Si se le asigna al grupo RT-CGM, les haremos algunas preguntas sobre el CGM (si son mayores de 13 años).

Para los miembros del hogar mayores de 17 años, si no están presentes durante su visita, le preguntaremos si está bien que los llamemos. Si está de acuerdo, les haremos preguntas por teléfono o correo electrónico. Le preguntaremos cuál es la mejor hora para comunicarnos con el miembro de su hogar. NO se recolectará información personal de salud sobre los miembros del hogar. El nombre, la relación con usted, la edad, el correo electrónico y el número de teléfono solo se utilizarán para contactar a los miembros del hogar que usted crea que podrían estar interesados.

No acepto que los miembros de mi hogar participen____

Acepto que los miembros de mi hogar participen si así lo desean____

Junta Asesora
Se solicitará a un número pequeño de participantes que formen parte de un consejo asesor. Esperamos mejorar las clases de diabetes y discutir cualquier desafío que las personas puedan tener al participar en las clases de diabetes y en las sesiones de telemedicina. Le pediremos a los 3 primeros participantes que se inscribieron y también a los 2 primeros participantes que dejaron de ir a las sesiones que formen parte del consejo asesor. Si estos eligen no participar, continuaremos preguntando al siguiente participante inscripto hasta que tengamos 3 participantes que hayan asistido a las sesiones educativas y 2 participantes que hayan dejado de asistir a las sesiones. Le haremos preguntas ya sea en un entorno grupal o individual, ya sea por tele-visita /zoom o por teléfono acerca de vivir con diabetes y cualquier barrera o dificultad que experimente. Las entrevistas durarán aproximadamente entre 45 a 60 minutos y se grabará el audio para garantizar que todas las respuestas sean entendidas/ recopiladas para luego resumirlas de manera general para abarcar a todos los participantes.

RIESGOS, ESTRÉS O INCOMODIDAD (MALESTAR)
¿EXISTEN RIESGOS EN ESTE ESTUDIO?

Los riesgos relacionados con su atención médica normal no se enumeran en este formulario. Le recomendamos que hable sobre esto con su médico del estudio, su proveedor de atención primaria u otro profesional de la salud.

Participar en una investigación implica algunos riesgos de daño o malestar físico o psicológicos. Siempre existe la posibilidad de que ocurran lesiones desconocidas o inesperadas.

Los riesgos más probables de este estudio se describen a continuación:

Monitoreo Continuo de Glucosa
El sensor CGM puede causar dolor cuando se inserta en la piel, como una inserción en el sitio de la bomba de insulina o una inyección de insulina. En raras ocasiones, puede ocurrir una infección de la piel en el sitio de inserción del sensor. Puede ocurrir picazón, enrojecimiento, sangrado y moretones en el sitio de inserción. Una alergia a la cinta que sujeta el sensor a la piel es posible. El riesgo de un problema en la piel podría ser mayor si usa un sensor durante más tiempo del que se supone que se debe usar. Existe la posibilidad de que el sensor o la aguja se rompan debajo de la piel. No se espera que esto ocurra, pero si ocurre, debe preguntarle al médico del estudio qué hacer.

Al igual que los glucómetros, o medidores de glucosa en sangre, que puede usar actualmente, es posible que el dispositivo CGM no proporcione una lectura precisa. Esto puede suceder debido a un mal funcionamiento, problemas con la batería o al apagar accidentalmente las alarmas. Si siente que la lectura de azúcar en la sangre de su CGM es diferente, debe revisar su nivel de azúcar en la sangre con el monitor de glucosa que su proveedor de atención primaria le haya proporcionado previamente para su control de la diabetes.

El uso de acetaminofeno (Tylenol) puede dar lecturas inexactas si toma más de la dosis recomendada de 3000 mg al día. Le recomendamos no tomar más de la dosis recomendada por día de este medicamento.

Con el dispositivo CGM, es posible que se sienta incómodo o inseguro sobre el uso de un dispositivo médico en su cuerpo durante 10 días seguidos.

Riesgo de Hipoglucemia e Hiperglucemia
Como una persona con diabetes, siempre existe el riesgo de tener un nivel bajo de azúcar en la sangre (hipoglucemia) o un nivel alto de azúcar en la sangre (hiperglucemia). Los síntomas de un nivel bajo de azúcar en la sangre pueden incluir sudoración, debilidad, temblores y no sentirse bien. Los síntomas de un nivel alto de azúcar en la sangre pueden incluir aumento de sed, cansancio, visión borrosa e irritabilidad. Las clases de diabetes le enseñarán cómo evitar niveles bajos de azúcar en sangre y qué hacer si esto sucede. Además, si ve niveles muy altos de azúcar, debe consultar a su médico de atención primaria para que lo ayude a controlar los niveles altos de azúcar.

Incomodidad de punción en el dedo
Cuando hacemos una punción en el dedo para la prueba A1C, es posible que tenga una ligera molestia en el sitio de la punción. Esto es similar a las punciones en los dedos que se hace cuando se mide el nivel de azúcar en la sangre. También existe el riesgo de mareos, moretones y posible infección con pinchazos en los dedos para la diabetes.

Cuestionarios y Medidas Clínicas
Le haremos preguntas sobre sus actitudes, sentimientos y comportamientos relacionados con la diabetes y en general. Aunque es poco común, es posible que algunas personas encuentren estas preguntas un poco molestas. Puede negarse a responder cualquier pregunta que lo haga sentir incómodo(a). Puede decidir no contestar preguntas, tomar un descanso o dejar de participar en el estudio en cualquier momento. Se tomarán muchas precauciones para mantener su información confidencial, pero esto no es una garantía.

Las clases de diabetes se brindarán virtualmente por Zoom, o en persona en una clínica de Seamar asignada. Los Navegadores del Paciente y los educadores de la salud (HE) utilizarán las oficinas/espacios educativos de Sea Mar para dirigir las sesiones. Las sesiones nocturnas pueden llevarse a cabo desde la casa del educador usando un espacio privado para garantizar la privacidad de los participantes.

Pérdida de privacidad
Recopilaremos los números de azúcar en la sangre de los CGM que le daremos. Tendremos información detallada sobre su diabetes y hábitos diarios de salud. Algunas personas pueden sentirse incómodas con esto. El equipo del estudio verá sus datos de CGM. También veremos la información utilizada para crear cuentas de estudio para las descargas de datos de CGM. Debido a que las clases de diabetes se llevarán a cabo en grupo, otras personas que asistan a las clases pueden verlo(a) y escuchar las preguntas que hace o la información que comparte.

Manguito de presión arterial: El manguito de presión arterial puede causar una ligera molestia cuando se infla, pero se desinfla en segundos.

Junta Asesora y entrevistas individuales: Puede ser que se ponga nervioso o le sea avergonzante hablar sobre porque dejó de ir a las sesiones o las barreras que no le permiten acceder al cuidado de salud con respecto a la diabetes. Si comienza a experimentar stress o molestias hablando sobre esos temas, puede elegir no contestar las preguntas, o tomarse un descanso, o finalizar la entrevista.

ALTERNATIVAS A PARTICIPAR EN ESTE ESTUDIO

Si no participa en el estudio, usted continuará con su tratamiento actual para la diabetes y control de azúcar en la sangre. Lo alentamos a discutir sus opciones con el personal del estudio, su médico de atención primaria u otro profesional de la salud que esté familiarizado con la diabetes tipo 2. Hay otras clases educativas disponibles en Sea Mar y otros centros de salud para el control/educación de la diabetes. Sin embargo, actualmente el CGM no es pagado por el seguro en pacientes con diabetes tipo 2 que toman menos de 3-4 inyecciones de insulina al día. Si desea usar un dispositivo CGM fuera del estudio, su proveedor de atención primaria podría recetarlo, pero tendría que pagar el costo total del CGM de su bolsillo (cada sensor cuesta $35-70 según el tipo de dispositivo CGM que esté usando).

BENEFICIOS DEL ESTUDIO

Puede haber un posible beneficio médico para usted si decide participar en el estudio, pero no es una garantía. Es posible que no reciba ningún beneficio directo por participar en el estudio. Las personas que participen en este estudio de investigación agregarán nuevos conocimientos que pueden ayudar a otras personas con diabetes tipo 2.

CONFIDENCIALIDAD DE LA INFORMACIÓN DE LA INVESTIGACIÓN

Toda la información que proporcione será confidencial. Sin embargo, si nos enteramos de que tiene la intención de lastimarse a sí mismo o a otros, debemos informarlo a las autoridades.

El personal del gobierno o de la universidad a veces revisa estudios como este para asegurarse de que se realicen de manera segura y legal. Si se lleva a cabo una revisión de este estudio, es posible que se examinen sus registros. Los revisores protegerán su privacidad. Los registros del estudio no se usarán para ponerlo en riesgo legal de sufrir daños.

OTRA INFORMACIÓN

¿QUÉ SUCEDE SI QUIERO RETIRARME DEL ESTUDIO O SE ME PIDE RETIRARME DEL ESTUDIO?

Puede negarse a participar y puede retirarse de este estudio en cualquier momento sin penalización ni pérdida de los beneficios a los que tiene derecho. Puede continuar recibiendo

atención médica no relacionada con este estudio. Le animamos a que hable con un miembro del grupo de investigación, para que ellos sepan por qué está interrumpiendo el estudio. Su decisión no generará ninguna penalización ni pérdida de atención médica. Puede continuar recibiendo atención médica no relacionada con este estudio. También podemos pedirle que participe en la junta asesora o que haga una entrevista de salida para que podamos aprender cómo mejorar el programa.

Si está embarazada, la retiraremos del estudio y no recopilaremos más datos. Le pediríamos que busque atención de su proveedor de atención primaria.

Devolviéndole los resultados

Recibirá los resultados de las pruebas de laboratorio (A1c). También podrá ver su nivel de azúcar en la sangre en tiempo real si está en el grupo RT-CGM. Si no está en el grupo RT-CGM, los educadores de salud de Seamar recibirán sus valores de azúcar en sangre al final del estudio y es posible que pueda revisar los resultados con su médico. Si dice en el cuestionario inicial que tiene algún pensamiento acerca de hacerse daño, lo llamaremos de inmediato y lo ayudaremos a obtener ayuda.

¿HAY COSTOS RELACIONADOS CON LA PARTICIPACIÓN EN EL ESTUDIO?

El estudio pagará solo por las pruebas relacionadas con el estudio. Los costos del tratamiento, visitas al consultorio y pruebas para su diabetes y otras condiciones médicas serán responsabilidad suya o de su compañía de seguros. Esto se considera un cuidado estándar.

El estudio pagará los costos de todos los suministros y procedimientos de investigación que tendrá específicamente para el estudio. Estos incluirán los materiales educativos y el sistema de CGM, sensores, y un podómetro si es necesario. Ocasionalmente, puede ver un mayor uso de datos o una pérdida más rápida de batería en su teléfono inteligente con el uso de la aplicación CGM (Clarity). Si esto sucede, notifique al equipo de investigación para que podamos ayudarlo con este problema.

Compensación

Si participa en el estudio, recibirá una tarjeta de regalo de $50 por cada visita de colección de datos, por un total de $150 si completa las tres visitas de colección de datos. Si se requieren visitas adicionales no programadas, puede recibir hasta $50 adicionales.

El miembro de su hogar también recibirá una tarjeta de regalo de $15 por completar la encuesta/cuestionario. Si se le pide que forme parte de una junta asesora para mejorar el programa de educación y la telemedicina, usted y el miembro de su hogar también recibirán una tarjeta de regalo de $50 por cada hora que pasen en la junta asesora (probablemente $100 por cada reunión o $200 dólares en total). Usted recibirá $50 por cada hora en la que usted participe en entrevistas de 1:1.

Como incentivo adicional por asistir a las sesiones educativas, se entregara una tarjeta de regalo por $25 por asistir a 4 sesiones educativas o más, Se entregara otra tarjeta de regalo por $25 por asistir a 8 sesiones educativas o más.

¿A quién puedo llamar si tengo preguntas, quejas o si estoy preocupado(a) por de mis derechos como participante?

Si cree que tiene un problema médico o una enfermedad relacionada con esta investigación, comuníquese de inmediato con la Dra. Nicole Ehrhardt o con otro miembro del equipo de investigación al número que se proporciona en este documento. Ella lo tratará o lo referirá para que reciba tratamiento.

Si tiene alguna pregunta sobre sus derechos como sujeto de investigación u otras preguntas, preocupaciones o quejas sobre la investigación o su participación en este estudio, debe comunicarse con la División de Sujetos Humanos de la UW al (206) 543-0098 o llamar por cobrar al (206) 221-5940.

Uso de datos y muestras

La información y/o las muestras que obtengamos de usted para este estudio podrían utilizarse para estudios futuros. Podemos eliminar cualquier cosa que pueda identificarlo de la información y las muestras. Si lo hacemos, esa información y muestras pueden usarse para futuros estudios de investigación o entregarse a otro investigador sin obtener un permiso adicional de su parte. También es posible que en el futuro queramos usar o compartir información del estudio que pueda identificarlo. Si lo hacemos, una junta de revisión decidirá si necesitamos o no obtener un permiso adicional de su parte.

Fuente de Financiamiento

Este estudio de investigación cuenta con el apoyo de una subvención de la Asociación Estadounidense de Diabetes. Además, Dexcom (el fabricante del dispositivo CGM que se utiliza en el estudio) ha proporcionado suministros de CGM a un costo reducido para el equipo del estudio.

Declaración del sujeto:

He leído este formulario de consentimiento y se me ha explicado el estudio de investigación. Mis preguntas han sido contestadas a mi satisfacción. Entiendo que al firmar este formulario, no he renunciado a mis derechos legales ni liberado a nadie de negligencia. Elegí ser voluntario para el estudio. He recibido una copia de este formulario.

No firme este formulario de consentimiento a menos que haya tenido la oportunidad de hacer preguntas y haya obtenido respuestas satisfactorias.

Si accede a participar en este estudio, recibirá una copia firmada y fechada de este formulario de consentimiento para sus registros.

Declaración de consentimiento del presentador

Le he proporcionado a este participante información sobre este estudio. Al participante se le ha dado suficiente tiempo para considerar su participación y he respondido a todas las preguntas que tenían. El participante indicaron que comprenden la naturaleza del estudio, incluyendo los riesgos y beneficios de participar.

_____

Nombre impreso del personal del estudio que obtuvo el consentimiento Fecha

_____

Nombre impreso del sujeto Firma del sujeto Fecha

Copias a: Investigador
Sujeto
Expediente médico del sujeto (si corresponde)

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

Researchers: **Principal Investigator:** Nicole Ehrhardt, MD
Title: Assistant Professor of Medicine
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Phone: 206-598-4882
Email: nehrhard@uw.edu

Contact person for subjects: Evelin Jones Research coordinator
Phone: 206-221-9369

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 <u>with</u> 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 **<u>with the following visits:</u>**

- 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. <u>Visit 1: Screening and Data Collection</u>

- 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 <u>with or without</u> 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.

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

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 <u>not</u> 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. <u>Study visit 3</u>

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.

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.

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)

Version 6.0, 2-22-23.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	page 2 145
	2b	All items from the World Health Organization Trial Registration Data Set	page 1 and 2
Protocol version	3	Date and version identifier	Not including please indicate if shoudl be added
Funding	4	Sources and types of financial, material, and other support	page 1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	page 1
	5b	Name and contact information for the trial sponsor	N/a
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	None/N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A see data monitoring

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	page 4-6 148-216
	6b	Explanation for choice of comparators	page 5 180-183
Objectives	7	Specific objectives or hypotheses	page 6 217-223
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	page 7 226-229
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	page 7 236=238
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	table 1 page 7 -page 8 intervention : page 11 333-334
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	page 11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	page 12 373-378
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	page 12 373-378
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12 373-375
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	page 10-11 305-330 table 3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	scheme figure 1 446

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	page 8 251-264
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	page 8 265-304
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	page 7 227-229
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	page 7 227-229
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	page 227 to 234
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	page 7 231-234
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	305-312 page 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	page 10 308-309

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	page 9 230-231
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	page 7 226-304
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	page 9 226-304
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	page 9-10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	i do not think we have this??
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	page 7 230
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	page 7
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	page 2 98
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	page 13 398
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/q
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	consent form spanish and english
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.