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Pilot study of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes

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RESEARCH PROTOCOL

TITLE: Pilot study of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring(RT-CGM) in a Latinx population with type 2 diabetes

A: Specific Aims:

Aim 1: Determine the impact of the *Compañeros en Salud* (Partners in Health) curriculum in conjunction with RT-CGM on glycemic control in Latinx patients with T2D. We will enroll 100 Latinx patients with uncontrolled T2D through a federally funded healthcare network across the Seattle region. Participants will be randomized to receive the *Companeros en Salud* diabetes self-management education and support (DSMES) intervention with or without RT-CGM (n=50 per group) over 12 weeks with an additional 12 weeks of follow-up.(control= blinded –CGM+ Education and intervention= RT-CGM + education). Study visits will be held at screening, baseline(0-4 weeks) and 12 weeks (+/- 2 weeks) and 24 weeks (+/-2) weeks. Participants in the blinded -CGM+ Education group will undergo blinded CGM for 1 week at baseline and for 10 days after each study visit. The primary outcome will be A1C. Secondary outcomes will include time in range as measured by CGM and other CGM indices, body mass index, waist circumference, and systolic and diastolic blood pressure.

Aim 2: Engage key stakeholders to optimize acceptability and minimize barriers to participation in the intervention. After 25% of participants have completed the intervention, we will convene a committee of stakeholders that includes study participants (both completers and non-completers), community providers, diabetes educators, and patient navigators. Key barriers and facilitators to the intervention will be identified by stakeholders, and the intervention will be amended based on stakeholder feedback. The impact of these revisions on participant engagement during the study intervention will be analyzed.

Aim 3. Determine the effects of the *Companeros en Salud* curriculum with or without adjunct RT-CGM on diabetes-related behaviors and distress. At baseline and 12-+/2 weeks and 24 +/- 2 weeks, participants will complete surveys capturing dietary behaviors, physical activity, and diabetes-related distress. Participants will be provided with pedometers, and activity data will be captured for 10 days following each study visit. **Sub-aim 3A**: As an exploratory sub-aim, we will examine behavioral changes in other members of participants' households through brief surveys. This sub-aim will provide preliminary data regarding a possible "ripple effect," the capacity for an intervention in 1 individual to affect health-related behaviors in other household members.

B. Background

The prevalence of diabetes in adults in the U.S. now exceeds 12%, with type 2 diabetes (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 a leading cause of blindness, chronic kidney disease, heart disease, and

amputations.[3] Although recent advances in pharmacotherapy for T2D offer promise for enhanced glycemic control and mitigation of diabetes-related complications, these therapies are prohibitively expensive for many individuals living with T2D.[4] In contrast, behavioral interventions for diabetes management have been shown to be cost effective and efficacious and, critically, not only improve glycemia but reverse diabetes-related pathophysiology.[5,6] 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] **Thus, expanded efforts to design and implement culturally specific behavioral interventions for diabetes management are urgently needed.**

Latinx populations are disproportionately affected by T2D, with a T2D prevalence that is 80% higher than in non-Latinx whites.[9] Moreover, Latinx individuals with T2D experience higher rates of diabetes-related complications including retinopathy and chronic kidney disease.[10] Latinx individuals with diabetes also face greater challenges to accessing medical care and pharmacotherapies.[11] **Consequently, delivery of a diabetes-focused behavioral intervention program that is accessible, culturally tailored, and data-driven for Latinx individuals promises unprecedented potential to meaningfully reduce diabetes burden in a profoundly impacted population.** The diabetes self–management education and support (DSMES) curriculum *Compañeros en Salud* (Partners in Health) is a multi-cultural and bilingual, 12-module program that was created specifically for Latinx populations to improve diabetes self-management. **Whereas clinical data strongly support the efficacy of culturally tailored curricula,[7-9] more efforts are essential to reduce barriers to the delivery of DSMES programs and to develop adjunct interventions to augment the impact of the program.** Real-time continuous glucose monitoring (RT-CGM) predominantly has been available to patients using multiple daily insulin injections, but we have shown its utility for patients on less intensive glucose-lowering regimens.[12] We propose novel delivery of *Companeros en Salud* via telemedicine coupled with RT-CGM to Latinx populations living with type 2 diabetes. We predict that this intervention will 1) lead to sustained, enhanced glycemic regulation, 2) minimize barriers to care, 3) improve established risk factors for diabetes-related complications, and 4) promote salutary nutritional and physical activity behaviors while reducing diabetes-related distress.

In Washington State, the prevalence of diabetes in Latinx individuals is a striking 14%.[13] Moreover, Latinx populations both nationally and locally suffer greater diabetes-related mortality and higher rates of both microvascular and macrovascular complications.[14-15] **Thus, interventions to reduce diabetes-related morbidity and mortality in Latinx populations with T2D are urgently needed.**

Diabetes self-management education and support (DSMES) interventions are effective for improving glycemic control through encouragement of behavioral changes that reduce the risk of diabetes complications and improve quality of life.[5-6] Culturally tailored DSMES curricula offer even greater promise, but clinical data on optimal approaches for implementing these programs are limited, with a particular scarcity of data in Latinx populations.[16,17] We have evaluated the culturally tailored DSMES intervention *Compañeros en Salud* in two previous studies[18,19] and pilot tested the intervention in Seattle.[20] These studies were team-based interventions that utilized promotores de salud/community health workers (CHWs) and diabetes educators in Latinx populations with T2D. Whereas our data support the efficacy of this intervention, they also demonstrate the need for additional tools to reinforce behavioral change and to support participants' self-empowerment. The use of real-time continuous glucose monitoring (RT-CGM) has proven a highly effective intervention for improving glycemia in patient with type 1 diabetes[21-24] but has limited availability in patients with T2D, particularly among individuals in underserved populations.[25,26] Our pilot data demonstrate both acceptance of and perceived benefit from RT-CGM in African-American[27] and Latinx individuals[20] with

T2D. Further, accessibility of DSMES programs has posed a key challenge in the past,[7-8] and the recent, widespread use of telemedicine[28] offers a novel strategy for addressing this barrier. **Therefore, we predict that delivery of the *Companeros en Salud* curriculum via telemedicine coupled with RT-CGM will improve glycemia and indices of T2D-related risk, promote salutary behavioral changes, and enhance patient self-empowerment while attenuating diabetes-related distress in Latinx individuals with T2D.** This study could establish a new, powerful strategy for improving T2D-related outcomes and provide the basis for advocating wider access to RT-CGM, particularly for underserved populations. Finally, our study will generate critical preliminary data regarding the potential for this intervention to reach other members of participants' households – a so called "ripple effect" – and thereby augment the impact of the intervention in the greater community. In total, our study will test a novel and integrated strategy for diabetes management that promises improved T2D-related outcomes in a profoundly impacted and underserved population.

Innovation

This project is innovative in a number of ways: **First**, we focus on a population that is underserved and disproportionately affected by T2D and related morbidity. **Second**, our study will constitute the first randomized controlled trial in the Latinx population to test the efficacy of culturally tailored DSMES delivered in conjunction with use of RT-CGM as a "booster" for this program. **Third**, our study not only will assess the effect of DSMES with CGM on glycemic control and indices of T2D-related risk but also will assess behavioral changes in participants and other members of the household. By gauging the "ripple effect" – that is, the influence that an intervention in one individual may exert on other members of family unit – our study will provide preliminary data regarding the potential, far-reaching effects that this intervention may exert in the Latinx community. **Fourth**, our study will generate critical insight into the utility of the use of telemedicine for diabetes management in underserved populations. Thus, the study will capitalize on the unprecedented increase in telemedicine utilization that occurred in 2020 due to the Covid-19 pandemic and promises a novel means of reaching underserved populations with diabetes for whom access to care has posed a critical challenge. **Fifth**, we propose use of Patient Navigators (formerly known as CHWs) to act as additional mediators in our intervention to improve communication between participants and providers, troubleshoot problems that arise during study participation, and enhance trust between participants and the healthcare system, a critical step toward improving outcomes for Latinx populations with T2D. Thus, our study emphasizes a team-based approach that promises greater acceptability and reduced barriers to DSMES interventions. Therefore, this innovative approach to diabetes management and patient empowerment could prove a highly effective strategy for improving T2D-related outcomes in Latinx individuals and, further, could provide a scalable model for improving care for all underserved populations with T2D.

C. Preliminary Studies

Delivery of a culturally tailored DSMES curriculum via telemedicine and a team-based approach can reduce key barriers to diabetes education. *Companeros en Salud* is an evidence-based, culturally informed DMSES intervention that has been evaluated in two clinical trials with Latinx and African-American adults.[18-19] *Companeros en Salud* integrates evidence-based guidelines from the American Diabetes Association Standards of Care with culturally tailored content. The intervention comprises 12 group meetings delivered by peer educators over 3 months. Focus groups with African American and Latinx adults with T2D informed the cultural tailoring, and Social Cognitive Theory[35] guides the change strategies. Participants gain knowledge and skills in blood glucose monitoring, medication adherence, and healthy lifestyles.[36] In a study with 151 African

American and Latinx adults, A1C post-intervention significantly improved by 0.8% among program participants (P<.0001).[18] In a subsequent study, intervention compared to 6 month delayed control, participants' A1C improved (-0.8% vs. 0%; $p \leq 0.01$) in conjunction with improved understanding of T2D self-management skills.[37]

The past year has witnessed an exponential rise in the use of telemedicine, and the ADA has issued a directive to utilize telehealth for diabetes education.[6] This directive mirrors our experience and discussions with local diabetes educators working in the community who are currently using telehealth. Remote options for diabetes-related education promise to remove key barriers to care, including limited transportation, childcare, and time. In the current proposal, we will offer DSMES education sessions remotely through Zoom telemedicine, thereby increasing access to a critical intervention. Further, we will address potential barriers to access by implementing a team-based approach that includes ongoing technologic and educational support from health educators and PNs[38,39] throughout the intervention.

Real-time continuous glucose monitoring (RT-CGM) alone improves glycemia and promotes behavioral change in individuals with T2D. CGM has been available for over 20 years, and use has increased. The ADA's most recent guidelines highlight that intermittent real-time or intermittently scanned CGM can be helpful for people using either non-insulin or basal insulin regimens.[40] However, CGM is not yet readily available to most patients living with T2D.[25,26] Previously, we have shown that with cyclical RT-CGM use over 3 months, unadjusted A1C fell by an average of 1.0% in subjects with T2D not using prandial insulin,[12] and 3-month A1C improvement was sustained for another 12 months without further RT-CGM intervention.[41] Another more recent study using intermittent flash CGM technology showed similar results.[42] Investigators Dr. Wright and Dr. Sinclair conducted a small, one group pilot study with 15 Latinx adults to evaluate the *Companeros en Salud* DSMES intervention in Seattle, WA.[20] 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 blood pressure (p=0.002). Satisfaction with CGM and the *Companeros en Salud* curriculum was high. For example, one participant stated: "This program was eye opening. I realize that I am not alone in this fight. I found new support. I think you may have found the next big thing for diabetes."

In Dr. Ehrhardt's pilot study (N=22) in a primarily (70%) African American population of patients with T2D not using prandial insulin, participants wore RT-CGM for two cycles and a total of 20 days; this duration was selected based on literature suggesting that CGM can generate behavioral change even after limited or retrospective use.[44,45] In our pilot data we found a 2 fold improvement in nutrition and increased activity as compared to controls although glycemic changes were less than expected.[27] Among the 13 of 15 participants who responded to the 6-month follow-up survey,[43] 100% reported that prior use of RT-CGM continued to contribute to a healthier lifestyle. Further, 92% reported that they would like to use the CGM device again, 46% reported 10 or more pounds of weight loss, and 84% continued to exclude certain foods from their diet and increase their physical activity.[43] In a just published, multi-site RCT including 50% minorities using RT-CGM, A1C level decreased significantly in the CGM arm. However, this RCT was not coupled to additional diabetes education, participants in the control arm were counseled to adjust insulin doses based on blood glucose data, and participants had to be on basal insulin.[47] Our 2012 RCT showed that RT-CGM use >48 days produced the most significant, sustained improvement in A1C;[41] consistent with this conclusion, our follow-up pilot data showed less robust changes in glycemia after only 20 days of RT-CGM use.[12,27] Additional research has highlighted that intermittent rather than continuous use of RT-CGM may be optimal for motivating and helping avoid burnout in patients living with T2DM.[44,46] As well, since our original data, RT-CGM now has longer sensor duration, better accuracy, and easy self-insertion. It also now enables viewing

of glucose data on a personal phone with data sent to a cloud-based storage system. Thus, these interim advances in CGM technology make it optimized both for personal use and as a tool in a community-based, virtual intervention.

However, the mechanisms whereby RT-CGM improves glycemia are incompletely delineated. In a prior study we found sustained glycemic response without escalation of medications that resulted from 12 weeks of RT-CGM use and persisted over 12 months.[41] We hypothesized that this sustained response occurred because of behavior modification, but our study did not capture nutritional or physical activity behaviors. Yet, a recent pilot study of 30 participants examined behavioral changes with RT-CGM and found that significant improvement in A1C was associated with changes in nutritional and activity behaviors at 5 months.[50] Similarly, our pilot data suggested that RT-CGM led to behavioral change[43]. For example, in our study, participants who consumed sugared beverages at baseline exhibited dramatic improvements in glycemic indices suggesting that reduced consumption of these beverages may have been a key facet of improved glycemia. Sugared beverage consumption is high among Latinx individuals and is "rooted in cultural identity and social norms."[51] **These data highlight that behavioral change may be an important mechanism through which RT-CGM could prove a particularly potent intervention in Latinx individuals with T2D.** ***The mechanisms whereby RT-CGM improves glycemia are incompletely delineated.*** In a prior study we found sustained glycemic response without escalation of medications that resulted from 12 weeks of RT-CGM use and persisted over 12 months.[41] We hypothesized that this sustained response occurred because of behavior modification, but our study did not capture nutritional or physical activity behaviors. However, a recent pilot study of 30 participants examined behavioral changes with RT-CGM and found that significant improvement in A1C was associated with changes in nutritional and activity behaviors at 5 months.[50] Similarly, our pilot data suggested that RT-CGM led to behavioral change[43]. For example, in our study, participants who consumed sugared beverages at baseline exhibited dramatic improvements in glycemic indices suggesting that reduced consumption of these beverages may have been a key facet[51] These data highlight that behavioral change may be an important mechanism through which RT-CGM could prove a particularly potent intervention in Latinx individuals with T2D.

Interventions that promote behavioral modification in an individual have the potential to impact other members of the household. Thus, spouses and partners of individuals with diabetes are at increased risk for developing T2D.[52-53] Children have a 20-40% absolute risk for developing diabetes if they have a parent with T2D[54] and are more likely to develop obesity if have family members living with obesity.[55] In fact, diabetes in a family member has been shown to have a higher positive predictive value for developing T2D than obesity.[56] This elevated risk is thought to result from a combination of genetic and environmental factors including shared nutritional and physical activity behaviors,[57] and particularly high risk has been identified in Latinx communities.[58] However, as health risks are shared among household members, the salutary effects of behavioral change also can impact other individuals in the family unit. Thus, family-based interventions have been shown to be effective for reducing childhood obesity,[59-60] and, notably, a meta-analysis concluded that parent-only interventions are as effective as parent-child interventions for mitigating childhood obesity.[61] Further, weight loss has been shown in spouses of patients who have undergone metabolic surgery or behavioral weight loss interventions.[62--64] Finally, limited data support the adoption of behavioral changes in family members of individuals with T2D who have undergone a standard diabetes education program.[65] Thus, a sub-aim of this study will explore whether a similar "ripple effect" is evident in the family unit of individuals who receive a culturally tailored DSMES curriculum with or without RT-CGM.

D. Research Recruitment and Population

Participant Recruitment: A maximum number of 120 eligible patients **will be** enrolled(with goal 100 completed) and randomized from Sea Mar health centers. The study will recruit from 6 primary care clinics (Des Moines Medical Clinic, White Center Medical Clinic, Federal Way Medical Clinic, Kent Medical Clinic, Seattle Medical Clinic, Burien Medical Clinic) given the high volume of Latinx populations who receive care at these sites. Additional participants may come from other Sea mar clinics. and from community engagement or the University of Washington clinics. Patients will be referred by their local primary care providers or by Sea mar health education team and their review of patients with uncontrolled diabetes or new diagnosis of diabetes in the Sea health system record. Patients who express interest will be contacted by telephone, email and/or in person by on-site research coordinators to ascertain interest and confirm eligibility criteria. Eligible individuals will be scheduled for their screening visit, ideally within 2 weeks of the contact.

Recruitment will be quarterly with one Spanish and one English speaking 12-week curriculum with a goal of 20-35 participants per DSMES cycle. We anticipate a roughly even distribution between English and Spanish speaking participants (e.g.,10-20 participants per cohort per language-specific curriculum cycle). A total of 4-6 DSMES cycles will need to be completed to reach 100 participants.

Recruitment information about the study will be made available to Sea Mar medical personnel including medical assistants, nursing staff, and physician and physician extenders at Sea Mar by medical staff announcements and provider flier (Appendix E). Information about the study will be made available to patients by a study flier (Appendix F) which will provide contact information for the study coordinator. If potential participants express interest in the study to medical staff, permission for the study coordinator to contact them via telephone or email will be requested and potential participants will be contacted for further screening and potential enrollment. As part of the diabetes health care team for Sea Mar, Sea mar Patient Navigator and health educators will pre-screen provider's clinics for potential participants and engage the participant at visit or the provider prior to the visit so the provider can assess if patient would be interested. A database search of UW clinics sand Sea mar clinics may also be used to identify potential eligible subjects and this information may be provided to the UW research coordinators in order to contact patients to discuss by telephone their interest in participating in the study. The UW coordinator or Seam Mar health team will ensure during phone call to:

1) Introduce themself.
2) make sure you are talking to the right person
3) say how you got a hold of their information
4) Explain the call is to discuss research study.
5) ask if now a good time is to talk
If voicemail: Voicemail: 1) Introduce self; 2) state only that they are calling about a UW study; 3) ask for a call back

Subjects may also be identified through posters and flyers placed in the community, as well as through all University of Washington clinics especially the Diabetes institute Latinx Clinic and in the

broader community through websites and other advertisements. Potential subjects who satisfy the study criteria and express interest in the study will be given information about participation either by mail, email or a phone call. Eligibility questions will be asked but no study related procedure will be performed until informed consent/authorization has been obtained (see Appendix C).

The study screening and research procedures will take place at the patient's home or in the health education office, or another Sea mar Clinic location, per patient preference. If possible, the visit will be performed in person, but given the increase in tele-health visits during the COVID pandemic, if a potential participant is unable to complete the screening visit and/or research visits in person, then tele-visits for the research visits will be offered.

Population:

We propose to perform an observational prospective study that will involve 100 subjects with confirmed type 2 Diabetes. There will be 50 participants in the RT-CGM+education intervention group and 50 in blinded-CGM+education group. Patients with type 1 diabetes as well as controlled diabetes <8.0 % will be excluded (8.0 or greater included). Sea Mar clinics care for more than 8,500 patients living with diabetes, and when the designated clinics were reviewed for Latinx patients with A1C ≥8.0%, over 460 potential participants were found. Thus, we will have a robust population for recruitment and diabetes self-empowerment. Additionally, participants may be found in the local community or UW clinics

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E. Statistical Considerations

Sample Size Estimation

In this study, we plan to enroll and include a total of n=100 study participants. The study is designed and sized first for assessing the primary endpoint of change in A1C from baseline to 12 weeks (Aim 1), and secondarily to assess the impact of RT-CGM on A1C. To assess statistical power, we assumed 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 and will result 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 HbA1c 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 HbA1c 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 was assumed throughout.

Data Analysis Plan

AIM 1: Our primary endpoint for Aim 1 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 TIR, mean glucose, mean amplitude of glycemic excursions, TAR, TBR, and coefficient of variation. 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). Secondary outcome measures of TIR, body mass index, waist circumference, and systolic/diastolic blood pressure will be similarly assessed 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,[49] 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

Aim 2: For this Aim, the primary outcome will be the difference in % of DSMES education sessions attended for participants who complete the study before and after the stakeholder convening. Additional endpoints will similarly assess the differences in the following metrics of participant engagement: % adherence to RT-CGM use, % of participants who complete all study visits, and % of eligible patients who enroll in the study.

Aims 3 and 3A: Change in nutrition - particularly change in sugared beverage consumption - is the primary outcome for Aim 3. Secondary outcomes will include steps/day average, reported walking, and diabetes distress. 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 effect of wearing RT-CGM will be assessed using the analytic framework from Aim 1. 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. For Aim 3, the effectiveness of the *Companeros 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). The outcomes of household members will be measured and assessed similarly but in separate generalized linear mixed effects models. For participants with participating 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 .

F. Inclusion/Exclusion Criteria

Inclusion criteria:

1. Participants must be adults 18- 60 years old
2. Self-identify as Latinx
3. Have had a clinical diagnosis of T2D within the last 15 years with or without medication use
4. Have an AlC ≥8.0% at screening
5. Be physically and cognitively able to use the home CGM monitoring device
6. Be willing and able to follow all other study procedures

Exclusion Criteria.

1. Duration of diabetes ≤ 15 years
2. Type 1 diabetes or latent autoimmune diabetes
3. Current use of prandial insulin
4. Any condition that prevents walking at least 1 city block
5. History of serious mental illness other than adequately treated depression
6. History of bariatric surgery or current participation in a weight management program
7. Current diagnosis of cancer or other serious or systemic medical condition
8. Significant active cardio- or cerebrovascular disease after review by PI
9. Pregnancy
10. Unable to read, understand, and sign the Informed Consent Form (ICF) and if applicable, an Authorization to Use and Disclose Protected Health Information form (consistent with Health Insurance Portability and Accountability Act of 1996 [HIPAA] legislation), communicate with the investigator, and understand and comply with protocol requirements.
11. Known history of hypoglycemia unawareness

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G. Diabetes Education Curriciulum and Education Session Process :

***Companeros en Salud* curriculum:**[48] The DSMES curriculum entails 12, 1-hour weekly educational classes[1] that will be led by CDEs and health educators (Appendix Q1). Each class will last 60-90 minutes, depending on class size and discussion by participants. 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. 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 so that materials can be read as scripted. This approach facilitates learning for participants with little formal education and ensures intervention fidelity. An instructor's manual will ensure that the facilitators use standard instructional content and methods to deliver information and activities. Group discussion, role-playing, problem-solving, and hands-on activities are included to encourage engagement and enhance learning.

Session	Topic
1	Glucose Balance
2	Diabetes Medications
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

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. At the end of each class a survey will be given to the participants for each session (Appendix Q2)

All educational classes will be conducted via the Zoom platform for telemedicine or in person at Sea mar classroom per patient preference in group setting. Zoom education sessions will be recorded and the zoom platform announces the session will be recorded prior to you joining the meeting Session recordings will not be used for research but only to allow you or participants to watch the recorded session if you miss the live education session. It is highly encouraged to attend all sessions live for maximum education opportunity. Patient Navigators from Sea Mar will act as digital navigators and, prior to first session through first home visit as detailed below, will ensure participants have working devices for classes and if needed will provide hot spot for the class. PN will be available for problem shooting for joining the sessions via telephone and if more than 2 sessions missed and no response from participants, PN will have option of second home visit to check on participant and any barrier for attendance.

Participants will receive a telephone and or text and or email reminder 24 hours before each scheduled intervention class. Participants will send their name and may only use their first name or pseudonym if preferred through the chat feature on Zoom to track attendance. At the conclusion of each class, participants will be asked to set a goal related to the presented topic and will complete a brief satisfaction questionnaire. At each subsequent class, the facilitator will ask participants to discuss their successes and challenges in achieving their goals. For participants who miss a class, study staff will make up to 2 telephone calls to check in and confirm attendance for the next session. If 3 or more people miss a class, the facilitator will try to schedule a make-up class before the next scheduled session. If fewer than 3 people miss the class, or if it is not possible to schedule a make-up session, materials for the missed class will be available as recording but live attendance via Zoom will be stressed. People who miss 4 consecutive classes or a total of 8 total classes will be considered dropouts. However, these participants will not be turned away from future sessions if they decide to attend. All participants will always be included in follow-up data collection, regardless of class attendance or retention.

H. Study Design

Screening: Interested volunteers will be pre-screened by telephone or in person in respective clinics or via televisit and then scheduled for a screening visit (week 0). If potential participants express interest, they will be provided an email address or phone number to call for more information. Alternatively, participants will be asked if they would like to be called to receive more information and are willing to provide their contact information to study staff. If after receiving more information, the potential participant is interested, then pre-screening questions (appendix C) will be asked. If still eligible, then a screening appointment will be arranged by study staff. If the participant is not interested in participating, the participant will continue standard diabetes care with their primary care clinic .

Study visits and intervention:

Baseline Visit/Visit 1. Base line visit is 2-4 weeks prior to Week 1, which is the start of education intervention. Week 1 is the first week of the education sessions. Baseline visit will occur in the participant's home or at a local Sea Mar clinic and/ or maybe a combination of remote and in-person. A research coordinator will review the full informed consent document, explaining study goals, procedures, and any potential risks in Spanish or English. Consent (appendix Z ?) will be obtained prior to any screening procedures being completed, and conducted in a quiet room or private televisit. Participant will be given ample time to ask questions, and a copy of the signed consent form will be given prior to start of screening visit procedures. Participants will fill out a contact form, including emergency contact (appendix Z1). Study staff will review medical history and medications and family history (appendix D), as well as all inclusion/exclusion criteria. Point of care A1C will be measured via point of care testing with a Siemens DCA Vantage A1C Analyzer, at LabCorp or quest for serum A1C if remote visit is completed. All women of child-bearing potential will undergo a urine pregnancy test either point of care or at LabCorp. Participants who meet criteria for enrollment and wish to proceed with study participation will be randomized to an intervention arm in unblinded fashion.

Remote Consent : If baseline visit is remote/virtual, the consent form will be sent to the participant via REDCap to be viewed and signed remotely. Subjects can also request that a paper copy of the consent be mailed to them before Visit 1. The informed consent discussion includes time for the potential participant to read over the consent form and to think about their questions. If the potential participant has questions outside of the Research Coordinator's scope, the potential participant will be offered a follow-up consultation with the Principal Investigator or Co-Investigator who can provide more information. As this is a minimal risk study, we will request a waiver of documentation of consent.

Randomization. The study biostatistician will generate a randomized sequence of treatment group assignments using stratified permuted-block randomization (random block sizes of 2, 4, 6) stratified by A1C >9.0% and ≤9.0%. Sequences will be stored at and delivered through the REDCAP study database at the UW. Research staff will obtain the next randomization once a potential study participant has been determined to be eligible and has signed the study consent form.

Vital signs, anthropometrics measurements, and demographic information will be collected, and participants will be asked to complete study surveys as further detailed below. Participants will be asked to use pedometers and keep them on their person as much as possible during waking hours. Baseline data will be collected no more than 3 weeks prior to the initiation of the DSMES curriculum, and pedometer data will be collected over 10 days immediately following the baseline study visit. Both groups will undergo blinded CGM with insertion by study personnel over the same 10 days following the baseline visit. Participants will then have a follow up visit from a Patient Navigator 10-14 days after the initial visit (detailed below) If less than 72 hours of CGM data is obtained at follow up PN visit participants will be asked to repeat blinded CGM. Participants will be asked to continue their customary dietary and exercise habits until initiation of the intervention

Follow-up study visits given in a community setting will be within an acceptable window for data collection and held at weeks 12+/-2 weeks and 24+/-2weeks (Visits 2: end of education intervention and visit 3:12 weeks after education intervention. The same procedures will be completed as described in detail below. Visits 2 and 3 also may be held in the participant's home or Sea Mar clinic according to the participant's preference and be completed through a remote RC visit with a PN in person visit to complete blood pressure, weight circumference and weight and A1c. The study team will continue to contact withdrawn participants to conduct an interview regarding barriers to study engagement.

Study Procedures

The following procedures will be performed at baseline (visit 1), (Visit 2) and (Visit 3): Anthropometric and vital sign measurements: **Height** will be measured by a Stadiometer. **Weight** will be measured using a SECA 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.

Concomitant medications: Participants will be instructed to bring all current medications (prescription, over the counter, and herbal or vitamin supplements) to each study visit. The research study coordinator will review and record these medications. Comorbidities: We will use patient self-report to document stroke, CVD (congestive heart failure, myocardial infarction, or coronary heart disease), peripheral vascular disease, peripheral neuropathy, renal disease, and retinopathy. Point of Care A1C: The DCA Vantage Analyzer tests for a quantitative determination of A1C in human whole blood and provides immediate test results from a finger prick of blood. If age <50 and female urine dipstick for pregnancy completed.

Pedometer: participants will be given a pedometer or if preferred use the one available on their smartphone. They will be asked to keep the pedometer or phone on them as much as possible during waking hours during the study. Data will be collected for 10 days after the first visit then for the 10 days prior for visits 2 and 3.

Continuous Glucose Monitoring:

Blinded CGM: All participants will undergo blinded CGM for 10 days at baseline a (2-4 weeks prior to start of education) and visit 3 (24 weeks [+/2 weeks]). The blinded CGM- education group will also complete blinded CGM for 10-day period at the end of the education intervention (visit 2: study weeks12 [+/-2 weeks]). Participants can mail blinded CGM devices back in self-addressed postage-paid envelopes provided at the initial PN visit and devices will be provided at the first PN visit.

RT-CGM: Participants in the RT-CGM arm will be asked to wear the device for a total of 50 days for 84 days during the 12 weeks of education sessions at intervals of 10 days on then 7 days off over 12 weeks. CGM data for 10 days will be downloaded after the completion of the 3rd RT-CGM wear session which should correlate approximately with the 6^{th} education session. The final period of RT-CGM use will begin on the day of the final session of the DSMES curriculum. Participants will undergo initial training by PN and can have assistance for the first device self-insertion and may request additional virtual, telephone, or in-person assistance from PN. In our experience, study participants readily assimilate the self-insertion technique and require negligible follow-up support for this procedure. RT-CGM data will be collected remotely using a cloud-based platform

Preparation for the study intervention: Patient Navigators (PN) from Sea mar health education team will engage participants no more than 2-4 weeks prior to the start of the DSMES intervention to ensure participants have a working technology platform for the education sessions and provide hot spot if able through one home visit with option for second if need to assess barriers to technology or attendance. For all participants, PN will teach simple CGM insertion (blinded and RT). For those who are enrolled in RT-CGM arm, the PN will set up a mobile app for the RT-CGM device. PN also will conduct a 1, 30-minute training session on CGM for participants in this study, with particular focus on the use of RT-CGM as a tool to understand food and activity choices. If RC is remote PN may also engage at visits 1, 2 and 3 to gather objective measurements (weight, blood pressure and POC A1C or participant may go to LabCorp/quest for the A1C) As well they well gather the 10 days baseline pedometer data

Study Procedures: Study Participants' Household Member: No protected health information will be recorded for household member. Demographics of relationship to study participant, age and sex and history of diabetes or prediabetes will be recorded at baseline visit. Email address maybe recorded in order to contact patients if verbal permission is given.

For both groups, at baseline (visit 1), visit 2 and 3 any available household members with minimum age 8 will be asked to complete two short questionnaires about nutrition and activity for those age ≥13 the starting the conversation and physical activity questionnaire that the participant was given will be used. For those household members 8-<13 the Habits questionnaire about lifestyle that has been validated for children will be used. After visit one and visit two,household members of the RT-CGM education group whom are over 13 years of age will also be asked to complete a short questionnaire. The questionnaire asks whether they are aware of the CGM in the household and if it influenced lifestyle changes.

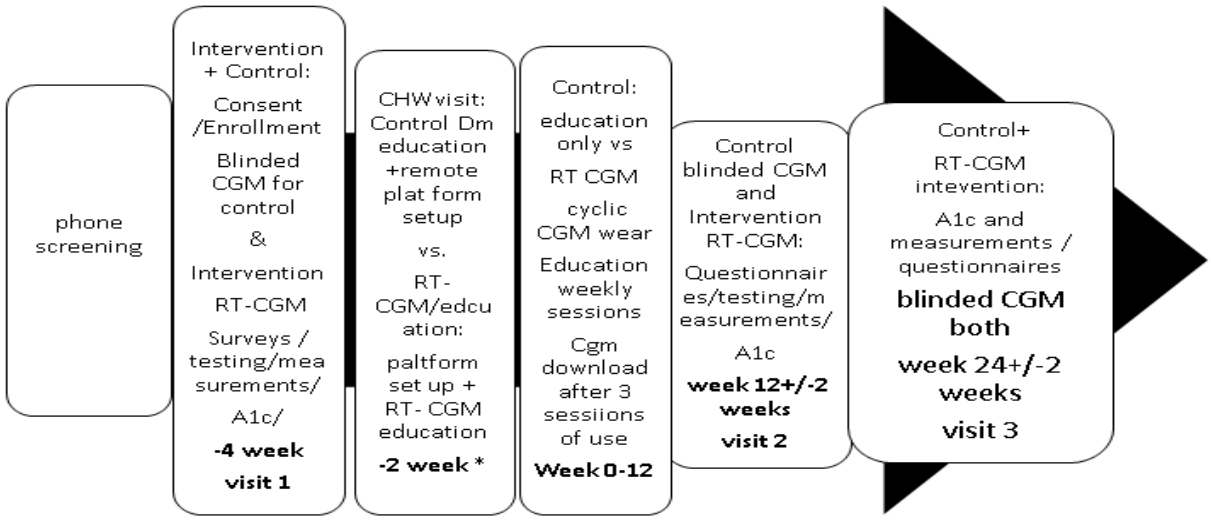

Figure 1: Study Design Schematic: N=100 Control N=50 (Blind-CGM-Education group) and Intervention group (RT-CGM-Education) N=50

***Approximate Total duration of CGM use would be 12 weeks goal 5 sessions 10 day wears over 12 weeks**

****measurents appendix B**

Figure 2: Study Timeline

Timeline in 6 Month Intervals							
Pre-Project Award							
Obtain Irb Approval							
Train research staff							
Intervention							
Recruit first 25 Participants							
Recruit 75 Participants							
Convene First Advisory Board							
Conduct Aim 1-3 and sub-aim							
Data Analysis & Dissemination							
Clean and manage data							
Analyze data							
Prepare manuscripts							
Project Phase	Pre	01	02	03	04	05	06

J.

Study Intervention Materials and Devices :

Televisits:

visits

Preference will be to conduct screening and all study visits in person at patient's home or at Sea Mar clinic However as COVID-19 pandemic continues more patients are using telehealth visits for routine care. If patient is not able to complete in home and clinic Sea Mar study visit within window, then the reseach visit will be scheduled via telehealth. The University of Washington uses the ZOOM platform which is HIPAA compliant and ensures patient privacy during the visit.

Medical Devices:

CGM (DEXCOM G6): A continuous glucose monitor (CGM) is a way to measure 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. A small plastic piece of tubing remains inserted in the skin. Typically, one cannot feel this tubing once inserted. It is connected to a transmitter that sits on top of the skin and is about the size of a quarter. It is attached or secured by medical tape to the wearer's skin. It is approved for use on the abdomen and has been shown to be effect for use on alternative sites such as upper buttock and arm for 10 days. The CGM either records the blood sugars and stores which we will then be mailed or returned at education session one or it sends the information via wireless radio frequency to a monitoring/display device or to a cellular phone so one can see their own data on their glucose, and we can download it remotely. The device automatically generates an alert for glucose < 55, and an alert will also be generated for glucose > 180 in the unblinded portion of the study. The intervention group participants will be given a handout (Appendix K) for troubleshooting these alerts, particularly during the blinded portion of the study. DEXCOM G6 is FDA approved for use in patients with diabetes and will be used in accordance with instructions as approved for diabetes. The risk is minimal with use of this device. In this study, we recommend patients connect the CGM to their cell phones. Study staff will insert the first sensor for the groups and then PN at digital navigation visit will demonstrate how to insert additional sensors for the intervention group who will continue to use RT-CGM and control group in case they need to self-insert blinded CGM. If this is to be done as a televisit, the sensors, transmitter, and device (if needed) will be mailed to the participant. Then the study staff will walk the participant through the first insertion through a virtual zoom visit. Patients will also have a youTube video available for reference for the patients. The patients will be instructed on how to remove the sensor themselves after 10 days and bring it back or mail back. The RT-CGM-education intervention group will wear the RT-CGM- cyclically and have telephone support and may refer to the youTube video on insertion if needed. The intervention participants will have RT-CGM download after 3 cyclic sessions of use and at 5 sessions of use. The Blinded-CGM education group participants will wear the blinded CGM at baseline and 24=/- weeks at conclusion of intervention. If, during the blinded portion of the study, due to device malfunction (rather than subject non-compliance), the device records less than 3 days of data, the participant will restart another 10 days of blinded CGM data.

The receiver and/or the app will display the glucose reading along with a rate of change arrow and a trend graph. Additionally, the receiver and/or app issues alarms and alerts to notify the patient of glucose level changes and other important system conditions. The app provides the additional capability to share data with "followers" using the Dexcom Share service.

CGM Ancillary Devices Dexcom CLARITY® is an accessory for users of the Dexcom CGM system. It is a software program that 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 study clinicians. Target ranges of 70 to 180 mg/dl will be set, and the patients will be introduced to the use of alarm settings. Both participants and study sites will use CLARITY® to transfer glucose data between user and study site, whether CGM is used in blinded or real-time mode. A CLARITY® mobile app can be used for a retrospective review of glucose data on the smart device and can also be set up to allow receipt of push notifications of CGM data facilitating data review. For all patients (intervention and control group) an anonymized CLARITY® account will be created by using a sequential study number which is allocated at randomization. Additionally, if participants desire The Dexcom G6 CGM System comes with a built-in Dexcom Share feature so you can let up to 10 people follow your glucose levels,

giving you a circle of support. By downloading the Dexcom Follow app, Followers can view your glucose data directly from their smart device

Intervention/ RT-CGM- education Group:
- For participants the DEXCOM G6 CGM app will be installed on participant's smart phone.
- An anonymized CLARITY® mobile account will be set up and linked to the research site.
.
- A high alert threshold will be set at 180 mg/dl and low alert threshold for <70mg/dl. In addition, the urgent low alert (55 mg/dl [3.1 mmol/l]), the urgent low soon alert (when glucose levels are falling fast and will be below 55 mg/dl [3.1 mmol/l] in less than 20 min) as well as alerts for rise and fall rate (3 mg/dl [0.17 mmol/l]) in addition to alerts for signal loss and no readings for more than 20 min will be enabled and patients will be shown how to turn off if they desire.
- Participants with applicable smart phones may have CLARITY® push notifications on the CLARITY® mobile app about weekly time in range comparison enabled during the study.
- For app users, the "Share and Follow" functionality will be discussed and encouraged (i.e., the study participants are able to invite followers to review their glucose levels).

Control/ Blinded-CGM-Education group

The participants of the control group will perform self-monitored blood glucose testing as indicated by their primary care provider with blood glucose meter as per typical care provided by their healthcare system.

At completion of study, 30 control group participants who express interest verbally will be given 3 Dexcom Real Time sensors. Data collected from these sensors will not be used for study activities. Participants will be made aware that they are responsible for reporting all glucose values collected by these devices to their Seamar clinical team.

RT-CGM Handout:
A simple educational handout has been developed to explain glucose goals and also how food and activity affects blood sugars. This handout will be reviewed with RT-CGM participants at PN visit(see Appendix A) and Appendix A2 for those not using RT-CGM

K .Measurements (Appendix B) :We will measure A1C at the beginning of the study period visit 1 weeks and A1C at visit 2 and A1C and visit 3. At each visit, blood pressure, resting heart rate, weight and height will be measured. For blood pressure and heart rate two values will be taken and the average used. At baseline and visit 2 and 3 , questionnaires on diet and physical activity and personal wellness questionnaires will be obtained. In the intervention group at visit 2 , a questionnaire about CGM technology and perception of benefit of CGM use will be obtained.

Anthropometrics: Height will be recorded in centimeters and inches by a stadiometer. **Weight** will be recorded in pounds and kilograms using a Digital scale. Two measurements will be taken, and the average will be used. **Blood pressure and pulse** are taken with an Professional Digital blood pressure machine. Two measurements will be obtained at each appointment. If performed via remote

televisit then patients will use their own blood pressure cuff and available scale.**Waist measurement** will be measured using a flexible tape measurer.

Pedometer data: Pedometers will be supplied to all participants at the baseline study visit or if preferred participants can use the step counting app embedded in their smart phone (Visit 1), and participants will be asked to wear the devices or keep their phone on them as often as possible during waking active hours. Data will be downloaded by PN in the participants' homes 10 days after the baseline, and for the 10 day prior to visit 2 and visit 3 -week. We will compare average steps per day over the 10-day period prior to visit 2 and visit 3 relative to baseline steps.

L.Collection of Human Biological Specimens:

Fingerstick and serum A1C: The HbA1c test is a blood test that provides information about a person's average levels of blood glucose over the last 3 months. The DCA Vantage Analyzer HbA1c assay tests for a quantitative determination of HbA1c in human whole blood, and provides immediate test results from a finger prick of blood. If remote visit is completed and CHW can not complete A1C then participant maybe asked to go to Labcorp to A1C meaurement

Dip Stick urine test: Dipstick urine test will be completed at screening if indicated with immediate results available to review or if needed can be completed at Labcorp

M: Questionnaires : All questionnaires will be available in REDCAP and completed at time of baseline visit with RC in person or remotely. For visit 2 and 3 Redcap surveys will be sent in advance and can be completed by participants in advance and then reviewed with RC or if not completed in advance completed during visit 2 and 3. Assent for household members will be on top of Redcap survey or read to person if in person or on the phone (Appendix N)

Nutrition questionnaire: Starting the Conversation (STC) is an eight-item, simplified food frequency instrument designed and validated for use in primary care and health-promotion settings. It asks respondents to estimate the number of times they consumed certain types of foods over the past week, including fast food, fruits and vegetables, and sugared beverages. Importantly, it has been used and validated in diverse populations including Latinx individuals.[66] (appendix G). It will also be used for household members >12 years old.

Physical activity questionnaire: The International Physical Activity Questionnaire (short) is a validated questionnaire that reviews the last 7 days of activity for adults including amount of activity and intensity.[67] This questionnaire will help capture types of physical activity often not captured by pedometers (i.e., yoga, resistance training, etc.) It will also be used age greater than 12 (Appendix H)

Six-item short form of the Food Security Survey[68]: The Six-Item Food Security Scale was developed by researchers at the National Center for Health Statistics. Respondents are asked questions, for example, about whether food cost or access was a limitation to their eating balanced meals, prevented them from eating when hungry, or caused them to skip meals. This survey will help provide

critical context for participants regarding the feasibility of implementing nutritional changes in response to the study intervention. (Appendix U)

Smoking and alcohol use: Smoking-related questions will distinguish current, past, and never smokers, including number of cigarettes smoked/day and age at initiation or cessation. Alcohol consumption will be assessed with questions about frequency and type of current consumption of alcoholic beverages.

The *Neighborhood Questionnaire/Neighborhood Safety*[69] *and* International Physical Activity Prevalence Study SELF-ADMINISTERED ENVIRONMENTAL MODULE(PANES):[77]
This neighborhood 16-item tool assesses sociability and an individual's satisfaction with the family's neighborhood. It has three subscales; Public Service, Social Involvement, and Neighborhood Safety. 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 and additionally ask questions 2,4,6,9,13,14 and 16 of PANES. (Appendix S)

Diabetes distress questionnaire: The Problem Areas in Diabetes Scale 5 (PAID-5) is a 5-item, validated short form of the PAID-20. The questionnaire consists of 5 items, scored on a 5-point Likert scale ranging from 0 (not a problem) to 4 (a serious problem). A cutoff of 8 or higher indicates elevated diabetes distress. A Spanish language version of this survey has been validated.[70] (appendix O)

Depressive symptoms questionnaire: The Patient Health Questionnaire 9 (PHQ-9) score ranges from 0 to 27, and higher scores indicate more depressive symptoms. Research studies have shown that a cutoff of 12 or higher is suitable to identify elevated depressive symptoms in patients with diabetes and have validated its use in Latinx populations. (Appendix P) [-71-72]

Post session educational session Questionnaire Q2

Performance of diabetes self-care activities: Performance of these activities will be assessed by 7 of 11 items in the Summary of Diabetes Self-Care Activities (SDSCA) appropriate for T2D. SDSCA measures the frequency of following a diabetes self-care routine during the prior 7 days in 5 domains: diet, exercise, blood glucose monitoring, foot care, and medication adherence. Item scores are averaged to yield an overall score (Appendix R).[73]

Self-efficacy will be assessed by the 8-item Stanford Self-Efficacy for Diabetes scale, which measures confidence in one's ability to conduct self-management activities, such as choosing appropriate foods or exercising for 15-30 minutes 4 or 5 times per week. Both surveys have been validated in Spanish(appendix T).[74]

CGM perception: Finally, participants in the T-CGM arm will complete 1 additional survey at the 12-week visit (Visit 2). Satisfaction with CGM and blood glucose monitoring: The Harvard Joslin Diabetes Center has developed a series of questionnaires on CGM experiences, opinions and expectations that will be given at the end of the intervention for participants in the RT-CGM arm only(appendix I and I2). Additionally, questions about nutritional and activity changes have been specifically created for CGM use (appendix J).

Logs**:** Participants will be asked to keep a food and physical activity log during blinded CGM at baseline and in the 10 day period after session 12 of education intervention. Logs will be optional but encouraged (appendix V

and W**).** They will also have a log to record their blood sugar as per their PCP recommendations for monitoring(appendix y)**.**

Household Children Nutrition questionnaire: For children less than 12 years of age. Habits food and activity[76] will be used to assess children's activity and food (appendix X).

Household member perception of CGM: a Questionnaire has been created to evaluate the household members age 13 and greater perception of CGM use by family member and behavioral changes(Appendix Z)

N: Glucose/CGM Data /Evaluation 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.

O. **Advisory Board**: We will convene key stakeholders in an advisory board after approximately 20-25% of participants have completed the 12-week intervention and again during years 2 and 3 of the study. The first convening will occur after 1 education cycle has been completed for both an English- and Spanish-speaking cohort, with an estimated 20-30 participants having undergone the intervention. Key stakeholders will meet specifically to address barriers to entering and completing the education intervention, implementing the behavioral changes recommended by the DSMES curriculum, and adhering to CGM use in the RT-CGM arm of the study. Accordingly, invited stakeholders will include patients who were eligible but opted against participation, participants who enrolled but did not complete the intervention phase of the study, participants who completed the 12-week intervention, and participant's household member if desires. Additional stakeholders are described below. The board will be asked to assess possible barriers to participant engagement, including the following: support for technology use, adequacy of RT-CGM training, food insecurity, safety concerns, and time commitment and sustainability.

Revisions to the study protocol that enhance access and engagement will be implemented for the remainder of the study period, and indices of engagement (% of eligible participants who enroll, % of education sessions attended, % of participants who complete all study procedures, % adherence to CGM use) will be measured prior to and after the changes implemented consequent to the stakeholder convening. Key stakeholders will be convened again in years 2 and 3 of the project. These meetings also will focus on barriers to sustaining the intervention, particularly with regard to the availability of essential resources (CGM devices; CDEs, health educations, PN, and other personnel; infrastructure to support remote education sessions, etc.) and therefore will be key for the design of future interventions**.**

Key stakeholders:

The advisory board will be chaired by Dr. Lorena Wright, MD, Director of the UW Medicine Diabetes Institute LatinX Diabetes Clinic. Other members will include PN and members of Ventanillas de Salud (a local chapter with the Mexican consulate that works to combat health disparities). In addition, Spanish-speaking diabetes educators, primary care providers, and a quality improvement officer from Sea Mar will be included in the board. Ten participants from the first two cohorts (5 from each cohort of participants (with the goal to include 2 participants who withdrew from the intervention). We will ask

the first 3 participants who enrolled and completed greater than 70% of the sessions to be on the board. We will also ask the first 2 participants who stopped going to the sessions to be on the advisory board. If they decline we will continue to ask the next participant enrolled until we have 3 participants who have engaged in the educational sessions and 2 participants who stopped attending the sessions.

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 questions either in a group setting or 1:1 tela-health interview about living with diabetes and any barriers/difficulties they are experiencing. Interviews will last approximately 50-60 minutes and will be recorded in order to ensure all answers are transcribed and then collated in a de-identified manner for QI for the program

The participants will participate in the first two advisory boards. In the second and third meetings of the advisory board, we will include representatives from one or more of the Medicaid Health Maintenance Organizations (HMOs) including Washington Health Authority (Apple Medicaid) .

P. Risks and Side Effects:

There are various possible risks and side effects that a participant may incur as a result of this study. At the beginning of the study, when participants are administered the informed consent form by research staff, they will be informed that their participation is completely voluntary and will be informed of the risks and benefits. They are free to leave the study at any time and will not be penalized. Potential subjects will also be told that failure to participate in no way affects the usual care they would receive from their PCP provider. Only after all questions have been answered, both study staff and the participant will sign and date the consent form.

It is very unlikely that there will be any adverse events

There are possible risks associated with the intervention activities, including the medical device, including:

a. Less Likely (1% ≤ Event Rate < 5%): CGM site infection or tape allergy (<1-2%) (41)
b. Likely (5% ≤ Event Rate < 10%): None
c. More likely (Event Rate ≥ 10%): None

There may be temporary discomfort with the device at insertion time. This can include bruising or redness of the skin, rare allergic reaction to the tape used to keep device in place, infection at site, and potential perceived dislike of having medical device on body for 10 days serially or continuously.

Participants may experience side effects from the fingerstick blood prick. There may be temporary discomfort including possible bruising or redness of the skin, lightheadedness, and on very rare occasion infection. People may experience embarrassment associated with measurements of weight and waist measurement. Minor discomfort may be experienced when answering questions that are personal in nature.

There is a rare risk that a breach of confidentiality could occur; however, every effort is made to prevent this from happening. In addition, every effort is made to perform assessment activities in a private and respectful manner by research staff who have been specifically trained to do them.

Plan for PHQ-9 Endorsement of Suicidality

We will be checking for completion of the questionnaires after links to participants are sent to them and the PHQ-9 responses will be checked at that time. REDCap will be set up so that the research coordinator (RC) is sent a notification when the questionnaire is completed. The RC will check the PHQ-9's completion within 1 hour after being notified if during business hours and within 1 hour of the next business day on the day it has been completed in REDCap. We will minimize likelihood of results occurring outside of business hours by sending surveys in the morning and avoid sending them on Friday as much as able based on participant timeline. Our plan will be put into action if any questions are answered in a manner concerning to our study personnel who will be trained for our action plan and what to watch for within an hour of seeing the answers to the questions.

If the subject endorses suicidal ideation by answering the question yes on the PHQ-9 questionnaire our plan is to:

- Call the participant immediately after review and discuss the participant's answer,
- Provide the participant the number for the local suicide hotline,
- Call the PI if the participant endorses the intent to hurt themselves.
- The PI of the study will be notified immediately and will make the decision to call 911.

The research coordinator (with at least a BS or BA degree) of the study will be trained by the PI who is a licensed MD in all aspects of this questionnaire. The PI be be taking responsibility for this plan of action

Q. Benefits:

Participants may receive some benefit for glucose control for diabetes with RT-CGM and education sessions which may or may not translate to improved long term outcomes complications from diabetes and sugar control. Control patients will likely receive no benefit from blinded CGM but have benefit from educational sessions. This research may benefit society by enhancing our understanding of medical devices use in patients not on prandial insulin especially coupled to education and thus help establish new procedures and practices that are associated with diabetes care

R. Conflicts Of Interest:

Dr. Ehrhardt is on an advisory board for Novo Nordisk about diabetes medications which was determined not to be a related COI by the University after review.
Dr Ehrhardt has also been on an advisory board for DEXCom but review by university determined it did not meet the criteria for significant financial COI.
Dr. Lorena Wright, Dr. Ka'mi Sinclair and Dr. Laura Montour have no conflicts of interest

S. Confidentiality:

All of the subjects' personal information, clinical data and consent documents will be stored in a secure location in a locked file cabinet in the University of Washington research coordinator's office. The subjects' personal information and research related clinical data other than routine laboratory results will be accessible only to the Principal Investigator and the research staff associated with the study. Organizations that may inspect and copy the participant information include the IRB of the University of Washington. A master code linking the unique study numbers with subjects' identifying information will be kept by the Principal Investigator or by the Project Officer in a locked file cabinet.

Additionally, all data collected by coordinators will be entered and managed through the encrypted Research Electronic Data Capture (REDCap) system maintained at University of Washington. All data is de-identified with no personal health information entered (PHI). REDCap was developed specifically around HIPAA security guidelines. REDCap has been disseminated for local use at more than 940 other academic/non-profit consortium partners in 75 countries. REDCap servers are housed in a local data center at CNMC, and all web-based information transmission is encrypted. This system is accessed through a secure login and password. Only the REDCap database coordinators and study staff will have access privileges to the University of Washington data set and will be strictly prohibited from sharing passwords. All will undergo the standardized authorized training provided by the REDCap team. Staff will maintain files in password-protected documents on HIPAA-compliant servers. REDCap programmers build in quality controls for the data that will be collected according to their stringent protocols. More information about the consortium and system security can be found at http://www.projectredcap.org. Data will be stored as per UW Records Retention requirements a nd for possible re-analysis and sub-group analysis that the clinical team may determine to be useful. This will allow time for the PI and collaborators to reexamine the data as needed in the revision process for manuscripts submitted to peer-reviewed journals.

All information that the study subjects provide study personnel is for research purposes only and, as such, names and any other identifying information will not be reported or published in papers, presentations, or proposals that result from this research.

When the subject enrolls in the study, they will be assigned a unique study number that is not any part of their social security number or other personal identifier. These unique study numbers will be used to identify all information that subjects provide and any information that is collected from their medical records. The unique study numbers will be assigned sequentially according to the order of study enrollment. Subjects will be identified by the initials of the group to which they are randomized and 3 numbers according to their entry into the study beginning with 001. Therefore, the first subject randomized to the DMC (control) group willl be DMC-001 and the first subject randomized to the DMCGM (intervention) group will be DMCGM-001. A total of 50 DMC and 50 DMCGM subjects will be enrolled.

Although every precaution is being taken to protect participant privacy, breach of confidentiality is always possible. In the unlikely event of a breach of confidentiality, the nature of the research data is not of a sufficiently personal nature to negatively affect employment status, lead to civil/criminal liability, incur financial risks to the study participants, or other risks.

T. Subject Compensation and retention: Retention. Shortly before each study visit, the research study coordinator will contact participants by telephone, text, or email to confirm their intention to attend the visit as scheduled or reschedule if necessary. Patients will also receive telephone call, text, and/or email reminders for the weekly education sessions 24 hours prior to sessions. Compensation. Participants will receive compensation at each study visit in the form of a $50 gift card.. If lack of CGM data necessitates unscheduled visits, the participant will receive an additional $25 per visit up to a maximum of $50 (if 2 unscheduled visits are required). Household members of participants will also receive a $15 gift card each time they complete the survey/questionnaire. If a participant or household member is asked to be on the advisory board they will receive a $50 gift card for every hour of of panel participation. There will be additional incentives for participants' continued participation in educational sessions. A $25 gift card will be given for attending 4 educational sessions, and an additional $25 gift card will be given for 8 or more educational sessions attended.

U. Appendixes

A1. Blinded Continuous Glucose Monitoring educational material
A2. RT- Continuous Glucose Monitoring educational material

B. Table of Study Measurements

C. Pre-Screening Checklist Telephone

D. Medical History and Screening Form-

E. Medical Staff and Provider Flie

F. Participant Study Flier- need Spanish version

G. Nutrition/Food Questionnaire need Spanish version

H. Physical Activity Questionnaire need Spanish version

I. and I2 and I3 CGM experience, expectations and opinions Questionnaire

J. CGM lifestyle Questionnaire

K. CGM Device Troubleshooting Handout

L. Adverse Events Log

M. Visit form

N: Household member Assent and script

O. Diabetes Distress Questionnaire Problem Areas in Diabetes Scale 5 (PAID-5)

P. PHQ-9 Depression Questionnaire

Q. Q1 Education Curriculum and Survey post session Q2

R. Summary of Diabetes Self-Care Activities (SDSCA)

S. The *Neighborhood Questionnaire/Neighborhood Safety*

T: Self-Efficacy for Diabetes scale

U The Six-Item Food Security Scale

V: Food Log

W: Activity log

X. Habits Survey

Y. Glucose log

Z. CGM household member/partner survey

Z1: Patient contact form

Z2: COLD Call Scrip

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