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Culturally Tailored Diabetes Self-Management Educational (DSME) Program and Its Impact on Motivation and Self-efficacy Among Hispanic Adults with T2DM: A Pilot Study

Andrellie P. van Wageningen

California State University, Northern California Consortium Doctor of Nursing Practice

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Culturally Tailored Diabetes Self-Management Educational (DSME)
Program and Its Impact on Motivation and Self-efficacy Among Hispanic Adults
with T2DM: A Pilot Study

Andrellie P. van Wageningen

The Valley Foundation School of Nursing

San Jose State University

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Author Note

This doctoral project is dedicated to my husband Darren for being my rock. Thank you for believing in me and allowing me to laugh out loud, cry frantically at times, and scream during some ungodly hours. To my four children, Hailey, Ally, Emily, and Vince, you all make me proud. You gave me tons of inspiration and love from the start to the finish line. This doctoral project is lovingly dedicated to my departed younger brother, Andre H. Punzal II. He gave me a lot of reasons to smile and tough through the difficult moments while balancing work, family, and school life. I would like to thank my doctoral project chair, Dr. Wei Chen-Tung, my program advisor, Dr. Robin Whitney, and practice mentor Laura Camberos-Medina. Thank you for always encouraging me and giving me support every step of the way. I would also like to thank my SJSU 2022 Spring Cohort for the kindness and generous help each time I needed it. To my specialty clinic and primary care chief MDs, nursing leaders, nursing staff, and executive team, this one is for you too. Finally, my family across the US and the universe, I could have not done it without you.

Abstract

Type 2 diabetes mellitus in the United States is an epidemic that disproportionately affects Hispanics in the state of California. Many factors have been attributed to this phenomenon because of their unique characteristics. As recent studies have pointed out, their social determinants of health, cultural influences, and genetic predisposition often lead to poor health outcomes and impaired quality of life. A targeted approach is critical in promoting increased diabetes knowledge, enabling skills to master self-care activities, and positive self-care behaviors to avert poor outcomes. The purpose of this doctoral project is to examine whether culturally tailored DSME influences an individual's self-motivation and self-efficacy levels (self-care behaviors), to determine whether the demographics have a relationship with self-care behaviors and to conduct a course evaluation. The pilot study utilized a single-group, prospective, quasi-experimental design with pre- and posttest intervention tests among ten Hispanic adults with T2DM at a county-operated specialty clinic. The study utilized two reliable and validated tools in Spanish to measure outcomes. The intervention showed a significant improvement in self-care behaviors, while the demographics showed an influence over these self-care behaviors over 6-8 weeks. The pilot study affirmed that a targeted approach is effective in activating positive behaviors among Hispanics with T2DM. The results of the intervention also highlighted the importance of promoting health equity through a structured DSME program. Further investigation is needed among the Hispanics with T2DM to identify barriers to self-care and for clinicians to develop culturally competent protocols to sustain the results of this study.

Keywords: Culturally tailored, diabetes self-care management, self-care activities, self-efficacy, self-motivation

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Chapter 1: Introduction

Type 2 diabetes (T2D) is now an epidemic in the United States (U.S.) with 34.2 million Americans diagnosed with this chronic, complex condition (CDC, 2020). The growing incidence and prevalence rate of T2D unequivocally puts persons with diabetes (PWD) at a higher risk for developing serious complications. The census continues to rise, especially among the Hispanics, who account for the largest minority group in the U.S. (18%), and their population is predicted to increase to 29% by 2050 (Office of the Minority Health [OMH], 2019; U.S. Census Bureau, 2018). Among adults aged 18-75 years, the prevalence of T2DM is higher (18%) (Caballero, 2005; Bullard et al., 2018; Golden et al., 2019) compared to non-Hispanic whites (NHWs) at 10% (American Diabetes Association [ADA] 2018; CDC, 2020). The situation is the same in the state of California, where more than 3.2 million individuals (9.4%) have been diagnosed with T2D and 384,000 Hispanics. California (CA) has the highest prevalence rate of T2D among Hispanics at 6.22%. In 2021, the CDC reported that diabetes is the 8th leading cause of death in the U.S. A recent study reported that T2DM-related deaths are 1.25 times higher among Hispanics than among other minority groups (Murphy et al., 2021; OMH, 2019), making T2DM the 5th leading cause of death among the Hispanic population (Statista, 2018).

Many studies supported that the Hispanic minority group is disproportionately burdened by T2DM (Butler, 2017; Dominguez et al., 2015; McBrien et al., 2017; Walker et al., 2016). Researchers highlighted that Hispanics experience challenges that hinder their ability to keep their diabetes well-controlled (Aguayo-Mazzucato et al., 2019; Cartwright, 2021; Zhang et al.,

2021). Their self-care management skills are also affected by their cultural beliefs, genetic predisposition (Anderson et al., 2016), and other socioeconomic factors (e.g., language barrier, education/literacy, socioeconomic status [SES] or occupation (CDC, 2020; Fernandez et al., 2011; International Diabetes Federation [IDF], 2017; Testerman & Chase; 2018) and health risk behaviors (Kamody et al., 2021). These factors increase the susceptibility of Hispanics with T2D to have poor outcomes (Hu et al., 2013; Chaufan et al., 2011). Poor outcomes include micro- and macrovascular complications, frequent hospitalization, and premature deaths (ADA, 2017; Aguayo-Mazzucato et al., 2019; Chandler & Monnat, 2015; Fortman et al., 2019; Laiteerapong et al., 201; Paneni & Lucher, 2017; Smalls et al., 2020).

Preventing untoward complications and improving quality of life are essential to T2DM management (Funnell et al., 2010). T2D management can be performed in several ways. One may start with getting diabetes education followed by lifestyle modifications such as changing eating habits or increasing physical activity (Acosta et al., 2021; Aschner, 2017). However, T2D is a complex, chronic disease that requires coordinated strategies called Diabetes Self-Management Education (DSME) to be well-controlled (Powers et al., 2016). DSME facilitates the acquisition of knowledge, mastering self-care skills, and performing self-care activities.

DSME is an evidence-based intervention critical to successful T2DM management (Pena-Purcell et al., 2015). DSME not only provides a solid foundation to guide persons with diabetes (PWD) to navigate through the complex process of self-care but also empowers PWD to participate in their care for positive outcomes (Bekele et al., 2020; Bruniholz et al., 2014; Chomko et al., 2016). With a structured diabetes self-management education program, T2DM-

related morbidity and mortality can be considerably decreased (He, et al., 2017; Chvala et al., 2016; Chandler & Monat, 2015; Powers et al., 2015; Attridge et al., 2014).

Background

National Standards for Diabetes Self-Management and Education (DSME)

The DSME National Standards were first introduced in 1984 and published by ADA and These standards typically encompass processes and outcomes directed toward rendering high-quality DSME services (e.g., patient care coordination, population health, or technology-based care models). Every five years, the DSME National Standards are reviewed and updated through the collaborative efforts of the Revision Taskforce. The group consists of 22 diabetes education experts from various health care disciplines. The task force is unique because it includes doctors, pharmacists, registered nurses, pharmacists, nutritionists and PWD. Each of them contributes to the extensive yet comprehensive body of knowledge necessary for translation into practice. Overall, these standards provide guidelines and recommendations that can be adapted by facilities regardless of the size or structure (ADA, 2022).

American Diabetes Association DSME Standards. The ADA continues to review and recommend guidelines on DSME. The ADA's DSMES aims to deliver person-centered care by integrating the concepts of social determinants of health and cultural preferences and adapting to evolving technological advancements and platforms (Davis et al., 2022). The ADA also recommended that DSMES be delivered at four vital intervals: (1) diagnosis, (2) annually, (3) when complicating factors affect self-management, and (4) when any transition in care occurs (Beck et al., 2017; ADA, 2017).

Association of Diabetes Care and Education Specialists (ADCES) Seven

(ADCES7). The Association of Diabetes Care & Education Specialists (ADCES) advocates for health care organizations to incorporate the seven self-care behaviors because of their positive impact not only on diabetes health outcomes but also on the quality of life. This framework consists of self-care activities such as regular monitoring of blood sugar, compliance with prescribed medications, use of good problem-solving strategies, healthy coping skills, and risk-reduction behaviors (Association of Diabetes Care and Education Specialists [ADCES] & Kolb, 2021). Furthermore, the ADCES self-care behaviors model fosters collaboration among the health care team to implement evidence-based interventions and best practices so that the quality of care is rendered optimal.

Chapter 2: Review of Literature

Culturally Tailored DSME and Positive Self-care Behaviors

Approaches toward the improvement of self-motivation (SM) and self-efficacy (SE) in diabetes management have been explored by researchers. A recent randomized controlled (RCT) study concluded that patient-centered interventions help increase the motivation and SE levels of patients with T2DM (Varming et al., 2019). Further emphasis on the benefits of self-empowerment was documented when compared to the use of prescription medications alone (Chen et al., 2019; Lee et al., 2016).

Self-efficacy. In the past, diabetes care was focused on medication management to help control hyperglycemia and reduce untoward complications (Khunti et al., 2012; Norris et al., 2002). Over the years, the practice has shifted toward focusing on providing patient education, facilitating the development of self-care skills, and confidently executing daily self-care activities (ADA, 2019; Brown et al., 2019; Funnell et al., 2012; Hildebrand et al., 2020; Nicoll et

al., 2014). However, a universal method may not target the specific needs of a PWD, especially with certain ethnic groups, such as Hispanics (Pena-Purcell et al., 2019).

Interestingly, despite the wide array of DSME delivery methods, the National Standards Taskforce did not endorse single-most or best methods (Barlow et al., 2002; Roter et al., 1998). This is because they recognize that psychosocial and behavioral aspects must be integrated, coupled with cultural-tailoring and age-appropriate strategies to be effective (Beck et al., 2017; Nam et al., 2012). Similarly, research studies affirmed that culturally tailored DSME is significantly impactful in eliciting self-care efficacy (Ji et al., 2020; McEwen, 2017; Mishali et al., 2011). Another study emphasized that the foundation of effective self-care management is SE (Beckerle & Lavin, 2013; Gao et al., 2014; Lorig & Holman, 2003; Odgers-Jewell et al., 2017). Furthermore, systematic reviews have consistently concluded that a coordinated, culturally specific intervention produces a favorable effect on patient health outcomes (Creamer et al., 2016; Flores-Luevano et al., 2020; Gutierrez et al., 2019; Hu et al., 2016; Joo, 2014; Lagisetty et al., 2017; Rosal et al., 2011; Zeh et al., 2012).

SE is one of the critical components involved in the successful management of T2DM (Shrivastava et al., 2013). SE means being able to check daily blood sugar levels, administer insulin, or take oral hypoglycemic medications and lifestyle adjustments to include a healthy diet, adequate nutrition, and regular exercise (Cooper et al., 2003; Inzucchi et al., 2012; Klein et al., 2004). Brown and colleagues (2016) also concluded that SE is the most consistent predictor of self-management adherence.

Self-Motivation. Gathering critical information before implanting culturally tailored DSME is critical in helping PWDs identify their barriers to being unmotivated, set realistic goals, and act upon these goals (Moore et al., 2019; Osborn et al., 2011). Another study established that

self-care management is positively influenced by highly motivated PWDs (Almutairi, 2020), those with an understanding of the disease and those who have the power to plan (Cuevas & Brown, 2018). Keers and colleagues (2006) reported that empowerment must be included in DSME because information about diabetes by itself does not generate positive self-care behaviors. Previous diabetes-focused researchers have also hinted that a low motivation level is the most significant factor contributing to poor SE (Casey et al., 2010; Peyrot & Rubin, 2007; Sarkar et al., 2006; Schmidt et al., 2020). With the abundant literature about the impact of culturally tailored DSME available, diabetes nurse educators have the power to stimulate, engage, and sustain efficient levels of motivation and SE and witness rewarding results (Bodenheimer & Handley, 2009; Greene et al., 2015; Miller & Bauman, 2014).

Demographics. There are approximately 10 million American adult women and 11 million men who have T2DM (Correa-de-Araujo et al., 2006; Mondesir et al., 2016); as a result, many researchers are urged to investigate the relationship between positive self-care behaviors and demographics. One study reported that it was possible to teach self-care management strategies but yielding positive self-care behaviors does not come without any challenges. These researchers also reported that many variables may negatively impact diabetes self-management (Adwan & Najjar, 2013).

Additional studies revealed that age (Di Bartolo et al., 2017; Riaz et al., 2014), sex (gender), marital status, education (Shigaki et al., 2010; Yazdani, et al., 2021), language (Pena-Purcell et al., 2011), and occupation (Dasappa et al., 2017) may influence self-care behaviors. As an example, Gonzales and her colleagues (2013) reported that Hispanic women and men have challenges in performing self-care activities secondary to low English proficiency (LEP), low literacy, cultural distinctions, and lack of access to care (Fernandez et al., 2011). In another

study, Hispanic women showed better results than men when performing self-care activities and when they have family, friends, and social support or “promotoras” (Brown et al., 2000). It was also reported that the active participation of family members and support systems are vital in promoting motivation and SE among PWD (Anderson et al., 1997), and SES had the greatest impact on the growing prevalence of T2DM among ethnic minorities such as the Hispanics (Marquez et al., 2019; Piccolo et al., 2016). Therefore, incorporating SES and cultural factors in diabetes education is imperative to establishing health-related goals, achieving optimal change in behavior, and improving diabetes quality of care (Aguayo-Mazzucato et al., 2019; Canedo et al., 2018).

Purpose of the Doctoral Project

The pilot study examined the relationship between the participants’ demographic variables and self-care behaviors (e.g., motivation and SE). The other purpose of the study was to explore whether a culturally tailored DSME program could improve self-care behaviors and conduct a course evaluation to obtain valuable feedback based on the participant’s perspective.

Significance of the Study

As previously stated, effective diabetes management requires a systematic and progressive approach because performing self-care activities has a robust influence on the patient’s well-being, QOL, and clinical outcomes. Poor performance of self-care activities can significantly aid the progression of T2DM, leading to complications. Therefore, it is critical to implement a structured program that incorporates cultural preferences, linguistics considerations, and other socioeconomic factors; otherwise, patients will be devoid of formal health education, unfamiliar of its value, and negligent in performing self-care activities (Maneze et al., 2019).

In addition, a myriad of studies has specified the positive effects of a culturally sensitive diabetes education program (Gonzalez et al., 2013). Understanding the factors that influence self-care behaviors and how they differ in the Hispanic population has resulted in the development of targeted intervention and facilitated the analysis of data to inform whether this type of intervention will foster improved patient outcomes.

According to the Office of Disease Prevention and Health Promotion [ODPHP] (2017), only 50% of adults aged 18 years and above with T2DM had received formal DSME. Healthy People 2020 also emphasized that formal DSME helps PWDs gain the knowledge, skills, and abilities required to effectively manage their condition (ODPHP, 2017). Increasing their T2DM knowledge is the first step toward self-care management, and cultural tailoring is critical to averting the problems associated with the Hispanic population (Pena-Purcell & Boggess, 2014).

The development of a culturally tailored DSME programme curriculum (Appendix L) based on ADA standards and ADCES7 and the implementation of this pilot study was intended to instill knowledge and elicit positive self-care behaviors directed toward self-care activity performance. Without instituting this pilot intervention, the health disparities experienced by the underserved Hispanic population seen at this clinic will be exacerbated, positive clinical and behavioral outcomes will worsen, and the quality of care will be suboptimal.

Theoretical Framework

The Transtheoretical Model (TTM) (Figure 1) and Self-Efficacy Theory (SET) (Figure 2) were the two theoretical frameworks used for this DNP project.

Transtheoretical Model (TTM)

Many disciplines have utilized the Transtheoretical model as a framework, including the health care field and T2 (Andres et al., 2008; TTM, n.d.). The transtheoretical model (TTM) postulates that individuals progress through six specific stages when changing health behaviors, as outlined in Figure 1 (Prochaska & DiClemente, 1983). The TTM assumes that individuals do not change behaviors immediately and definitively; instead, behavior change occurs continuously through a repeated process ((TTM, n.d.)

Managing T2DM requires deliberate and repeated efforts by the patient to initiate healthy behaviors. Therefore, the TTM framework helped assess the readiness of the project participants' motivation level and ability to make lifestyle modifications. By utilizing the TTM constructs, the project laid the foundations of behavioral change by promoting or individualized goals that were necessary to activate their motivational domains and sustain the positive results (Burke et al., 2014).

Self-Efficacy Theory (SET)

The foundation of the concepts of SE was derived from social cognitive theory (SCT), which depicts the interaction between personal, environmental, and behavioral factors in health and chronic disease (Bandura, 1977). Alfred Bandura defined SE as the individual's ability to perform goal-directed behavior based on their confidence level and overcome difficulties in performing the said task (Howells, 2002). Furthermore, the theory is believed to provide an important perspective on social support and health values based on the individual's cultural ideals (Thojampa & Mawn, 2016).

Change is not often welcomed by PWDs. Based on SET (Figure 2) concepts, the individual's motivation to do self-care activities has a direct relationship with their perceived self-

confidence (Bandura, 1977). The results of the pilot study indicated that a culturally tailored DSME program can empower participants, thus increasing the participants' SE and consequently improving outcomes. The investigator combined the constructs of TTM and SET to develop a conceptual framework (Figure 3). With this approach, the intervention was expected to support the participants going through the continued process of self-care behavioral change and gaining help to overcome the challenges impeding their ability to perform self-care activities (e.g., healthy dietary choices, do physical exercise, check regular blood glucose checks, and adhere to the medication regimen).

Chapter 3: Methods

Design

This project was designed as a single group, quasi-experimental with pre- and postintervention surveys. The focus of the pilot study was the implementation of a culturally tailored DSME program delivered in a small, one-on-one classroom environment. The study curriculum was based on the current DSME Standards from ADA and ADCES. The Institutional Review Board of the investigators' hospital reviewed the study protocol; however, the pilot study was approved as a quality improvement project instead (Appendix A). No university IRB approval was needed.

Study Participants

The participants were selected based on the following eligibility criteria: (1) age 18 years or older to understand the self-reported instrument tools and answer them clearly, (2) Hispanic/Mexican ethnicity, (3) diagnosis of T2DM, (4) approved referral for DSME from a primary care provider or diabetes care provider, and (5) Spanish-speaking. Patients with a

diagnosis of pregnancy, gestational diabetes, cancer, and end-stage renal disease were excluded from the pilot study.

The subjects were enrolled in the program voluntarily by the clinic's Hispanic, bilingual diabetes nurse educator between February 7, 2022, and April 8, 2022. The participants were allowed to invite one family member/support member to attend the class without taking part in the study's data collection proceedings. The call attempt thresholds were set to a maximum of three times. The eligible participants who exceeded the threshold were dropped from enrollment.

Study Locale

The pilot study was implemented in a not-for-profit academic, Specialty Care-Ambulatory Clinic in Santa Clara County (SCC). This facility specializes in diabetes care among the underserved population living within the SCC communities. The clinic is staffed with six endocrinologists, two nurse practitioners, one pharmacist, two nonbilingual nurse educators, and two bilingual, Hispanic diabetes nurse educators. Support staff consisted of registered nurses, licensed vocational nurses, medical assistants, and front desk clerks who assisted in daily workflow with respect to their job scope.

Both sessions were conducted at the Specialty Care Clinic's large conference room equipped with state-of-the-art audio-visual (AV) equipment. Institutional social distancing and infection prevention protocols were strictly observed in the classroom environment.

Instrumentation and Outcome Measures

The paper survey was offered in Spanish. The survey tools were already available in the Spanish language from their respective authors (Appendix B and Appendix C).

Demographic Data. Self-reported sociodemographic data such as the participant's age, sex assigned at birth, marital status, highest educational level, language spoken, ethnicity, and the number of years with T2DM.

Motivation and Attitude Toward Changing Health (MATCH) Questionnaire. A self-report survey tool with nine questions (Appendix C) was used to determine the three critical domains that impact an individual's ability or commitment to change health behaviors. The three domains include the following: (a) willingness to make the change (three items, Q #1, 4, and 7), (b) perceived *ability* to make or maintain a change (three items, Q# 2, 5, and 9), and (c) belief regarding whether change is truly *worthwhile* (three items, Q# 3, 6, and 8) (Hessler et al., 2018). The tool has a 5-point Likert scale with responses (1 = "strongly disagree", 2 = "disagree", 3 = "neither agree nor disagree", 4 = "agree", 5 = "strongly agree"). Questions 2, 3, 5, 6, 8, and 9 are worded negatively; therefore, items with lower values reflect better self-motivation. All responses on each item are added to determine the motivation level from the domains; a score of 30 represents a good SM level, and a score of 20 indicates a low motivation level (Hessler et al., 2018). This tool did not require any licensing fee to use. However, the investigator opted to secure permission to use the tool through an e-mail from the author (Appendix D).

Stanford Diabetes Self-Efficacy Scale (DSES). The 8-item DSES (Appendix C) was used to assess the confidence level of individuals with diabetes in performing self-care activities. The tool format is a 10-point Likert scale, from 1 (not confident at all) to 10 (totally confident). The first four (4) items address diet and exercise behaviors, while the remainder are more focused on blood sugar monitoring and diabetes health. The calculation of the SE score is gathered using the means of the 8 items. A score of 7 and above means good SE (Ritter et al.,

2016). This tool also did not require any licensing fee to use. However, the investigator opted to secure permission to use the tool through an e-mail from the author (Appendix E).

Course Evaluation Tool. A two-question, yes or no answer type course evaluation tool (Appendix F) was completed by the participants after completing the two DSME sessions. This tool was used to gather the participant's satisfaction with the instructor and the program's course content. The course evaluation feedback will be used for future course development or revisions as needed.

DNP Implementation Phase

Following the IRB proceedings, pertinent information was shared to the clinic's leadership through email (Appendix Q). An in-depth in-service among the DSME providers was given by the study personnel during the staff meeting.

Participant Recruitment. The participants were recruited using two mechanisms: (a) primary care physician and allied diabetes health professional referrals (diabetes nurse educator/registered nurse [RN], registered dietitian [RD], or pharmacist [PharmD], and nurse practitioner [NP]), and (b) self-referral by patient or family member. The participants were contacted by the study personnel (e.g., bilingual diabetes nurse educator, diabetes nurse coordinator, or principal investigator [PI]) via telephone, and preliminary consent was obtained (Appendix G). The participants were then enrolled to attend the first DSME session. The participants' appointments were confirmed one day before by the member of the study personnel.

Implementation Description. The classroom procedures included the following steps: (1) The participants were given instructions to arrive at least 15 minutes before the start of the class and (2) checked in by the clinic registration staff per clinic protocol. (3) The pretest MATCH in Spanish (Appendix B), DSES (Appendix C), and informed consent (Appendix H) in

paper format were handed to the participants upon checking in and were taken to the classroom to meet the class instructor (bilingual diabetes nurse educator). (4) The participants were ample given time to review the forms (e.g., consent and outcome tools), while the instructor remains available with clear instructions on how to fill out and assist them with any questions or clarifications. and ask questions before completing the forms. (4) The instructor reviewed the form to ensure that no data elements were missing. Following this, (5) the survey tools were collected and kept secured in a locked file cabinet in the PI's private office. The file cabinet was only accessible to the PI. (6) The instructor used AV equipment to present the first session's course content. The course content was in Microsoft PowerPoint (Appendix K).

The first session was approximately 90 minutes and covered the basic concepts of T2DM, DSME overview, current ADA DSME Standards of Care, and the first four of ADCES7 (Appendix M), namely, taking medications, monitoring blood sugar, problem-solving, and healthy coping. Pop quizzes (Appendix I) were embedded at the end of each concept for recall and reinforcement. (7) The participants were scheduled for the second session before sending them home with instructions for the next class along with the \$25 gift card (Figure 4).

One week after the first DSME session, steps 1 and 2 were followed from the first session. Steps 3 to 5 were not performed in the second session. Step 6 was also performed in session two, but the instructor focused on reducing risks, healthy eating, and being active. The participants were given instructions on the postintervention procedures before sending them home (Figure 5).

Four weeks later, the class instructor contacted the participants to collect the postintervention surveys (Appendix B and Appendix C) over the telephone. The two-question course evaluation (Appendix F). The instructor transcribed the participants' responses in the

paper format. The final \$25 gift cards and course manual (Appendix J) were mailed to the participant's home address.

Data Collection. The independent variable in this project was the culturally tailored DSME. The dependent/outcome variables were the participants' SM and SE scores. The preintervention survey tools were used for baseline data and were compared to postintervention data. At the end of the program, participants were asked to evaluate the program as previously described.

Continued Assessment. The investigator monitored the progress of the project regularly. The investigator established an open line of communication between the university Project Chair/Program Coordinator, study personnel, VSC Diabetes/Endocrine Clinic leadership, and class instructors throughout the pilot study. The ongoing communication was done through an exchange of e-mails, face-to-face meetings, frequent MS Teams video conferences, and quick telephone calls. These methods ensured that the PI and study personnel were engaged and committed to identifying challenges and problem solving in a timely and collaborative manner.

Statistical Analyses

SPSS (Statistical Package for the Social Sciences) version 27 and Intellectus Statistics were used for the analysis of statistical data. Descriptive statistics were used to describe the sample characteristics and differences between the outcome variables (e.g., stages of change [motivation level] and SE level). The impact of the intervention was measured using paired sample t tests. The mean scores were compared to identify if there was a change between the pre- and postintervention motivation and SE levels. Pearson coefficients were used to calculate the relationship between the demographic data and SM/SE levels. The investigator also performed data validation by conducting range/format checks, consistency or missing data entry, and

mismatched data type. Intellectus Statistician consultation was also utilized to ensure data integrity and results from validation. The results were regarded as significant if p values were ≤ 0.05 .

Chapter 4: Results

Demographics

The response rate was 30%, with only 10 out of the 34 eligible patients completing the two-part pilot study. A relatively high DSME class attendance is not uncommon because of the several contributing factors present in the Hispanic ethnicity. Some of the issues related to underuse and attrition include lack of access to DSME services, transportation barriers, low perceived seriousness of diabetes, competing priorities in life, forgetfulness, and apathy (Gucciardi et al., 2008; Peyrot et al., 2009). With the program's low attendance, there is a need to pursue further analysis of variables so that class instructors can develop and implement effective strategies to encourage continued attendance and active participation (Nguyen et al., 2017).

Table 2 shows the frequencies and percentages of the categorical variables (demographics). Most of the participants were between the ages of 41 and 63 years (80%). The participants were 100% Hispanic, Spanish-speaking, and born in Mexico. There were 70% females. Half of the participants (50%) had type 2 diabetes mellitus for more than a decade. The majority were divorced 70%, and only 30% finished high school (HS).

Paired t test Results

Table 7 illustrates the results of the two-tailed paired sample t tests and was significant based on an alpha value of .05 [$t(9) = -4.37, p = .002$]. This finding was a good indicator that

there was a statistically significant increase in SM and SE after completing the two culturally tailored DSME sessions.

Pearson Coefficient

A significant positive correlation was observed between preintervention MATCH (self-motivation) and DSES (self-efficacy) scores, with a correlation of .83, indicating a large effect size ($p = .018$, 95.00% CI = [.42.96]). This suggested that as the preintervention self-motivation (SM) level increases, the preintervention self-efficacy (SE) also tends to increase. A significant positive correlation was observed between pre- and postintervention DSES scores, with a correlation of .83, indicating a large effect size ($p = .018$, 95.00% CI = [.41.96]). The interpretation of this finding was synonymous with the SM scores as described. No other significant correlations were found (Table 8).

Course Evaluation

All participants (100%) rated the bilingual diabetes nurse educators and course materials to be helpful in improving their self-care behaviors or ability to perform self-care. Similarly, all participants (100%) stated that they would recommend the program to their family and friends.

Chapter 5: Discussion

We implemented a culturally tailored DSME program in a specialty clinic where most of the patients seen were Spanish-speaking Hispanics. The first significant finding of this pilot study was that culturally tailored DSME showed an increase between the pre-SM ($M=4.12$, $SD=0.51$) and pre-SE levels ($M=6.59$, $SD=2.10$) and post-SM ($M=4.71$, $SD=0.36$, $p = 0.002$) and SE ($M=9.41$, $SD=0.53$, $p = <0.001$) levels among all participants. The study demonstrated that culturally tailored DSME can lead to improved SM and SE when done consistently (Funnell et al., 2010).

As an example, the four-week interval was adequate to motivate and empower our participants to do well in performing diabetes self-care activities. We also believe that this finding was comparable with the conclusion of Rutten and colleagues (2020), where a targeted diabetes care platform may impact self-care behaviors, but a substantial outcome improvement is not achievable within the short range. However, the results support the value of focusing on a specific population (Noar et al., 2007) rather than the one size fits all arrangements (Davis et al., 2011).

Additionally, the marked improvement in their self-care behaviors can be associated with the theoretical framework of this study. Through this intervention, our instructors were able to assist the participants in going through the stages of change (TTM) and developing competencies (SET) directed toward self-care (Powers et al., 2017). Upon receipt of information, knowledge became available, which helped establish goals and set priorities by utilizing the resources available to them (O'Donnell et al., 2018). After attending the sessions, our participants were able to apply the concepts they learned in the classroom and participated in their care confidently. However, further analysis of the significant changes could not be attained because of the small sample size and short duration of the study. Future innovative studies on self-care behaviors are suggested with a focus on SM or SE constructs, and methodical integration into DSME practice would be beneficial to the implementation of care coordination protocols (Juarez et al., 2021; Mohebi et al., 2013).

This pilot study was evidence-based and patient-centric. The change in the SM and SE scores after the intervention could be attributed to the strengths of the study: (1) language-concordant speaking instructors, (2) culturally concordant instructors, (3) culturally competent program curriculum, and (4) linguistically appropriate medium of instruction. The study by

Nguyen et al., 2017 concluded that culturally tailored course content and engaging social support groups promote active participation. A similar study advocated for culturally competent diabetes staff because of its effect on self-care behaviors (Rothschild et al., 2012).

In addition, our study participants experienced an intervention that was novel to the study location. The curriculum was interactive and well structured, which enabled active and experiential learning. The program also added value to the participants' problem-solving skills (Peek et al., 2012; Piccinino et al., 2017) and adherence to treatment (Thakurdesai et al., 2004). Last, the results of the pilot study align with the research findings on patient-centeredness. Patient-centric diabetes care means the integration of evidence-based models of practice, patient education programs, and self-care management (Fredericks et al., 2012; McMullen et al., 2015; Olesen et al., 2020).

The pilot study examined the relationship between demographics and self-care behaviors. We observed an increase in pre-SM ($M=4.22$, $SD=0.51$) in males when compared to the post-SM ($M=4.81$, $SD=0.13$), and the same trend was noted between the pre-SE ($M=6.12$, $SD=2.32$) and post-SE ($M=9.25$, $SD=0.7$). The female participants showed an increase from pre-SM ($M=4.08$, $SD=0.55$) to post-SM ($M=4.67$, $SD=0.43$) and from pre-SE ($M=6.79$, $SD=2.16$) to post-SE ($M=9.48$, $SD=0.5$). However, the standard deviation of SE was observed to have consistently clustered for both males and females following the intervention. This finding was consistent with the study by Rucci et al., 2021, where sex or sex had no significant impact on SE. We agree that this may warrant further investigation to identify the contributing factors between the sexes and describe its impact on self-care behaviors. We also recommend that future researchers design sex

specific DSME among ethnic groups and understand its effect on self-care behaviors (Burner et al., 2013; Caruso et al., 2020).

We only had two age ranges observed, 41 to 63 years old and 64+. Among those aged 41 to 63 years, there was an increase in post-SM ($M=4.67$, $SD=0.39$) from pre-SM ($M=4.26$, $SD=0.47$), and the same results were noted in the post-SE ($M=9.58$, $SD=0.45$) when compared to the pre-SE ($M=7.38$, $SD=1.45$). Regarding the 64+ years, the results were very similar, showing an increase in post-SM ($M=4.89$, $SD=0.00$) from pre-SM ($M=3.56$, $SD=0.16$). The pre-SE ($M=3.44$, $SD=0.09$) also increased following the intervention ($M=8.75$, $SD=0.18$). Despite the limited self-efficacy of the elderly (Jakubowska et al., 2020), we concluded that senior participant patients were less motivated than those between the ages of 41 and 63. As illustrated by the pre-SE score, the 64+ group felt that they may be too old to control T2DM and often have had trouble keeping pace with the demands of self-care management.

Older Hispanics tend to be disproportionately impacted by T2DM (Mier et al., 2012) and frequently struggle with adhering to diabetes treatment/care (Nelson et al., 2018). Consequently, it was also reported that poorly instructed and low empowerment in older adults was less likely to result in superior self-care behaviors and self-management skills (D'Souza et al., 2017; Ramachandran et al., 2004). In contrast, improved self-efficacy was found to be significantly associated with younger PWDs (Alberti et al., 2005; Sari et al., 2021). Therefore, individual, and sociocultural factors need to be further evaluated, and age specific, evidence based DSME programs for Hispanic elders should be designed at the community level to improve behavioral and clinical outcomes (Mayberry et al., 2016; Haltiwanger, 2012).

In analyzing marital status, the pilot study had seventy percent married participants, and thirty percent were divorced. We observed an increase from married pre-SM ($M=4.21$, $SD=0.49$)

to post-SM ($M=4.86$, $SD=0.14$), and the same similar pattern was noted from pre-SE ($M=6.75$, $SD=2.34$) to post-SE ($M=9.46$, $SD=0.59$). The divorced patients also had a parallel trend with increased values from pre-SM ($M=3.93$, $SD=0.61$) to post-SM ($M=4.37$, $SD=0.53$). Equivalent observations were noted in the pre-SE ($M=6.21$, $SD=1.73$) and post-SE ($M=9.29$, $SD=0.47$) of divorced participants. From these figures, it can be inferred that marital status can influence self-care behaviors.

We agree with researchers who suggested curating a DSME program involving not only the PWD but also the family, social support, and members of the healthcare team to be effective and yield positive outcomes (Gobeil-Lavoie et al., 2019; Hildebrand et al., 2020; King et al., 2010). Our intervention also allowed a family member to attend the classes yielding to the participant's positive learning experience as reflected in the course evaluation tool section. By doing so, we were able to predict possible deficits at the beginning of the intervention, urged them to establish their self-care goals, and assisted them in progressively transitioning to the home environment. The explanation for the consequent findings was not further investigated because marital status and the presence of social support were not the focus of the study. However, we recommend ongoing research studies aimed at examining the value of family involvement and potentially expanding their interventions in various community settings (Escolar-Pujolar et al., 2018; Mohebi et al., 2018), especially in hard-to-reach regions (McElfish et al., 2015).

We also analyzed the evidence of low educational attainment. None of the patients studied had an educational background beyond HS graduation. Among the elementary graduates, we observed an increase in the SM level from ($M=4.03$, $SD=0.60$) to post-SM ($M=4.70$, $SD=0.42$), with analogous results in pre-SE ($M=6.09$, $SD=2.34$) and post-SE ($M=9.39$,

SD=0.63). Participants who finished HS had comparable results in pre-SM (M=4.33, SD=0.00) and post-SM (M=4.74, SD=0.23), as well as the pre-SE (M=7.75, SD=0.65) and post-SE (M=9.46, SD=0.29).

We concluded that those who had HS diplomas felt better improvement in their SM and SE compared to those who were elementary graduates. This finding resembles the published studies by Hwang & Shon in 2014 and Huang et al., in 2014, where educational level showed an impact on the ability to perform self-care activities and improve self-care behaviors. The patient population seen at this clinic was mostly in the low SES bracket; therefore, the class instructors and PI collaboratively revised the curriculum beforehand and ensured that the course materials were at the fifth-grade literacy level. This step was helpful in the predetermination of their socioeconomic barriers (Wolff et al., 2016). A few scholarly works also provided clarity on the relationship between low literacy and self-care behaviors and called for the development of means and techniques that would foster improved behavioral and clinical outcomes (Brunk et al., 2017; Swavely et al., 2014).

The results for the duration of T2DM and self-care behavior were categorized into three groups (Table 2). The mean scores in pre- and postintervention SM for both ranges showed improvement, but the most notable findings were from the marked difference in the mean scores for the participants with T2DM durations of 2-5 years and 10+ years. The mean SE scores of those with T2DM for 2-5 years jumped from (M=8.04) to (M=9.75) and 10+ years pre-SE (M=6.25) to (M=9.32). From this, the investigators noted that the individuals who had only been dealing with T2DM for 2-5 years started with a high SE score and those with T2DM for over 10

years were inversely proportional. This might have been indicative of a feeling of exhaustion or hopelessness because they have had T2DM for a while now.

We correlated the findings with the emotional and psychological demands of self-care management and control of T2DM (Kalra et al., 2018). Because of the small sample size and short duration of the study, we recommend further investigation to fully understand the impact of diabetes self-care management experience on motivation and self-care efficacy. With a few studies indicating that there is a connection between self-care deficit and diabetes-related stressors (Kim et al., 2015), it is critical to determine whether strong emotional and psychological regulation is an effective skill for long-term T2DM management (Dos Santos et al., 2020).

Limitations

There were several limitations in the study. First, the data were collected from a small convenience sample of Hispanic adults with T2DM, and the pilot study duration was only eight weeks, which limits the generalizability of our findings. Second, COVID-19 pandemic regulations and policies in place limited the possibility of holding large group sessions. Third, the quasi-experimental design of this study and randomization cannot be used, which limited the study's ability to conclude a causal relationship between an intervention and the outcomes (Schweizer et al., 2016). Furthermore, a control group was needed to evaluate the impact of the intervention on self-care behaviors among Hispanic adults with T2DM. Fourth, the investigator did not collect information regarding diabetes self-care knowledge, socioeconomic factors such as employment, social support, and additional cultural variables that may influence their ability to perform self-care activities toward positive health behaviors. Fifth, the study locale only has two bilingual nurse educators with multiple responsibilities, which limited the availability of classes only two times a

week. Sixth, the study did not include clinical indicators such as A1c and BMI secondary to the short study duration. Collecting these clinical indicators would be ideal if the study were extended for a few months. Moreover, the pilot study was implemented in one location. This limited the recruitment of participants. Finally, more qualitative work is needed to explore the factors associated with low enrollment or class completion rates. Despite these limitations, the strength of this pilot study is that it intensified the importance of effective evidence-based intervention, targeting a minority group that is disproportionately affected by T2DM.

Chapter 6: Conclusion

This pilot study demonstrated that a culturally tailored DSME program significantly improved self-care behaviors involved in performing T2DM self-care activities and confirmed that demographics influence self-care behaviors. Our participants rated the program to be satisfactory, relevant, and helpful in improving their self-care behaviors. With the power of evidence-based intervention presented in this study, we were able to give our participants access to a formal DSME program and foster better outcomes amidst the COVID-19 pandemic. However, additional research using robust designs is needed to address the limitations of the research using a methodical and systematic approach, especially the low response rate. The investigators hope that the study will encourage researchers to engage in similar studies to institute quality standards protocols, augment health outcomes, and influence diabetes-related health policies.

The study intervention introduced the concepts of cultural competence and humility at the study location; therefore, we would like to sustain the momentum by expanding the project across the satellite clinics under the Santa Clara County Health and Hospital System (SCVHHS). Finally, we hope that this pilot study could open doors to secure funding from federal, state/local

governments, and other not-for-profit organizations to design and develop innovative studies, especially for those who have limited or no access to diabetes care.

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Appendix

Figure 1

Transtheoretical model

Transtheoretical Model: Stages of Change

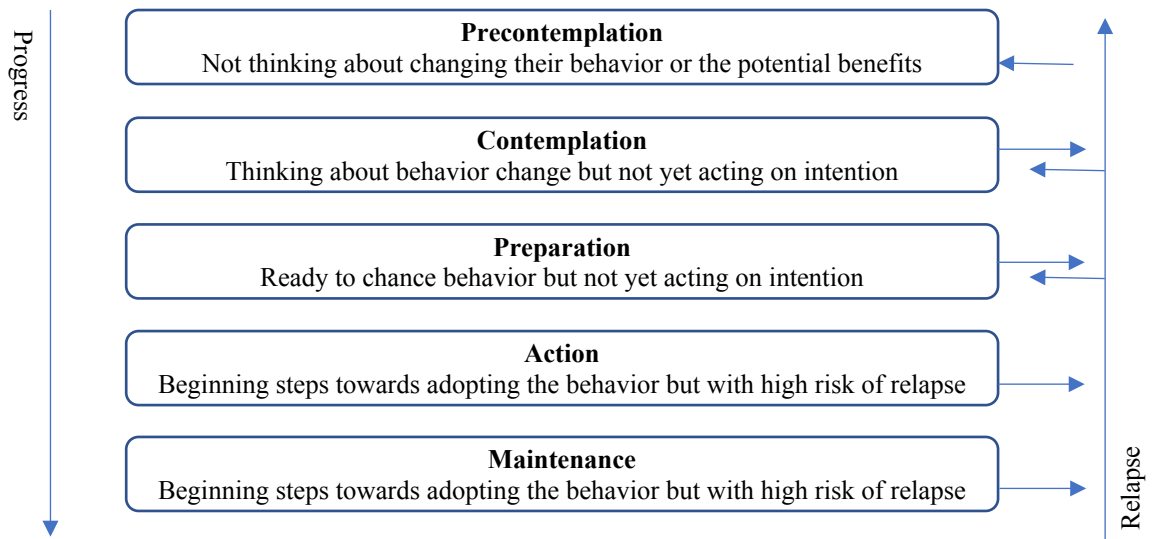


Figure 2

Self-Efficacy Theory

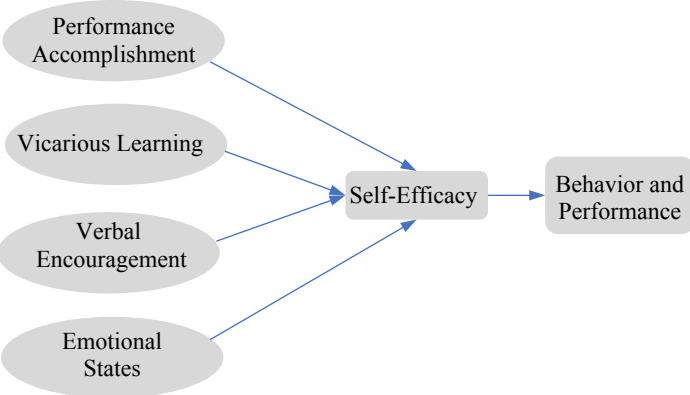


Figure 3

Conceptual Framework

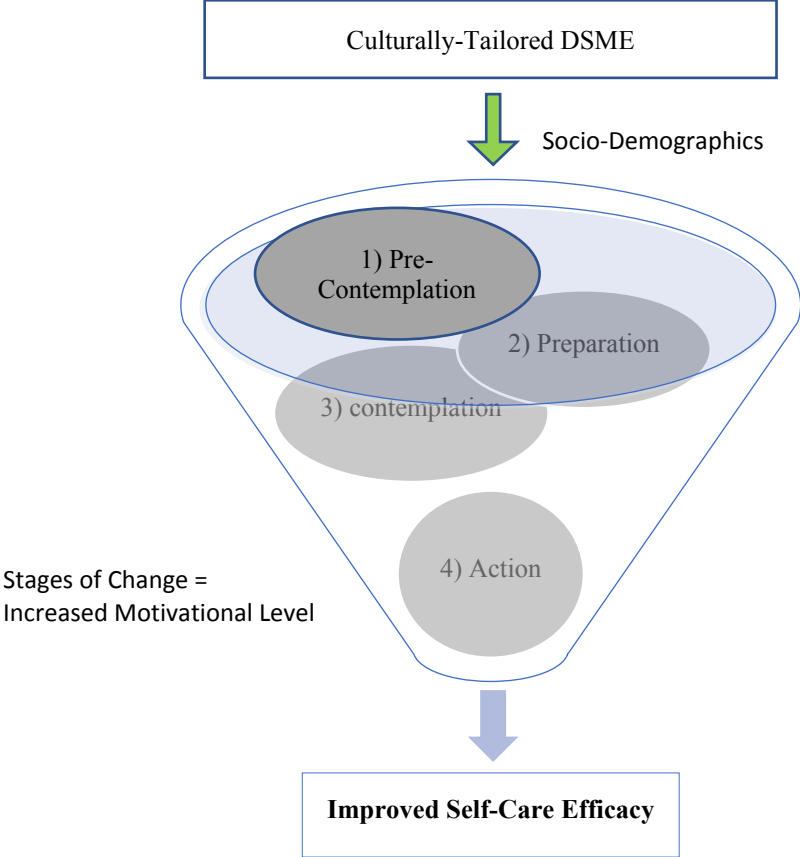


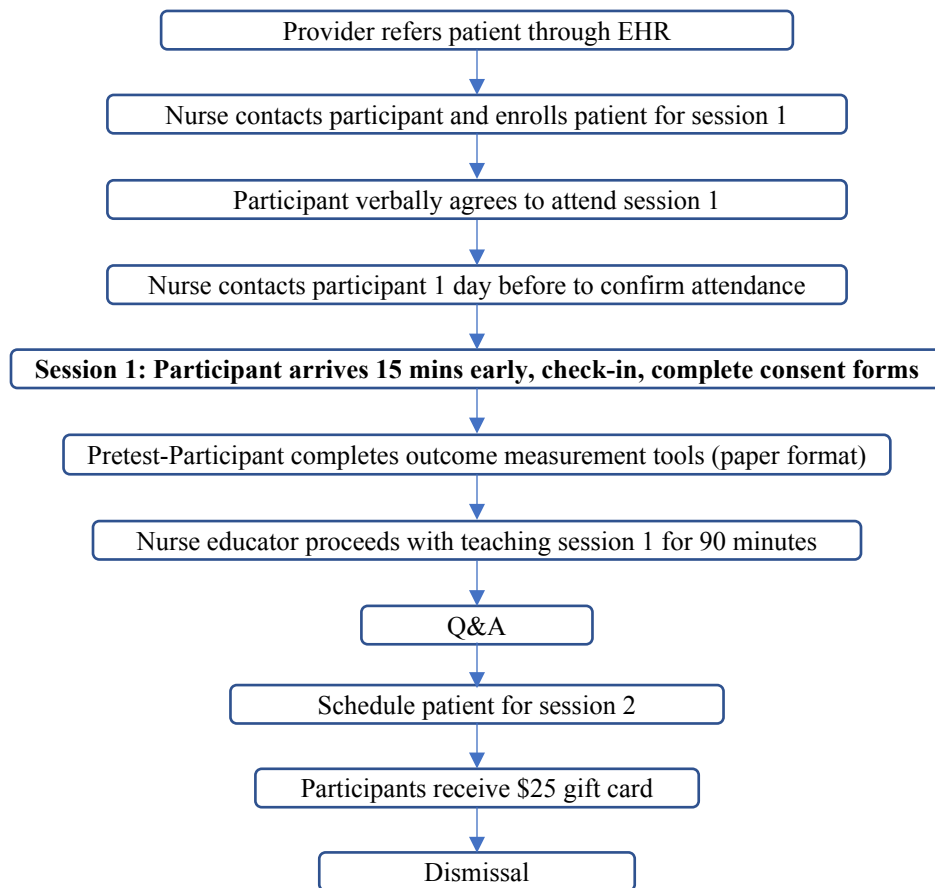
Figure 4*Intervention Flow Diagram Session 1*

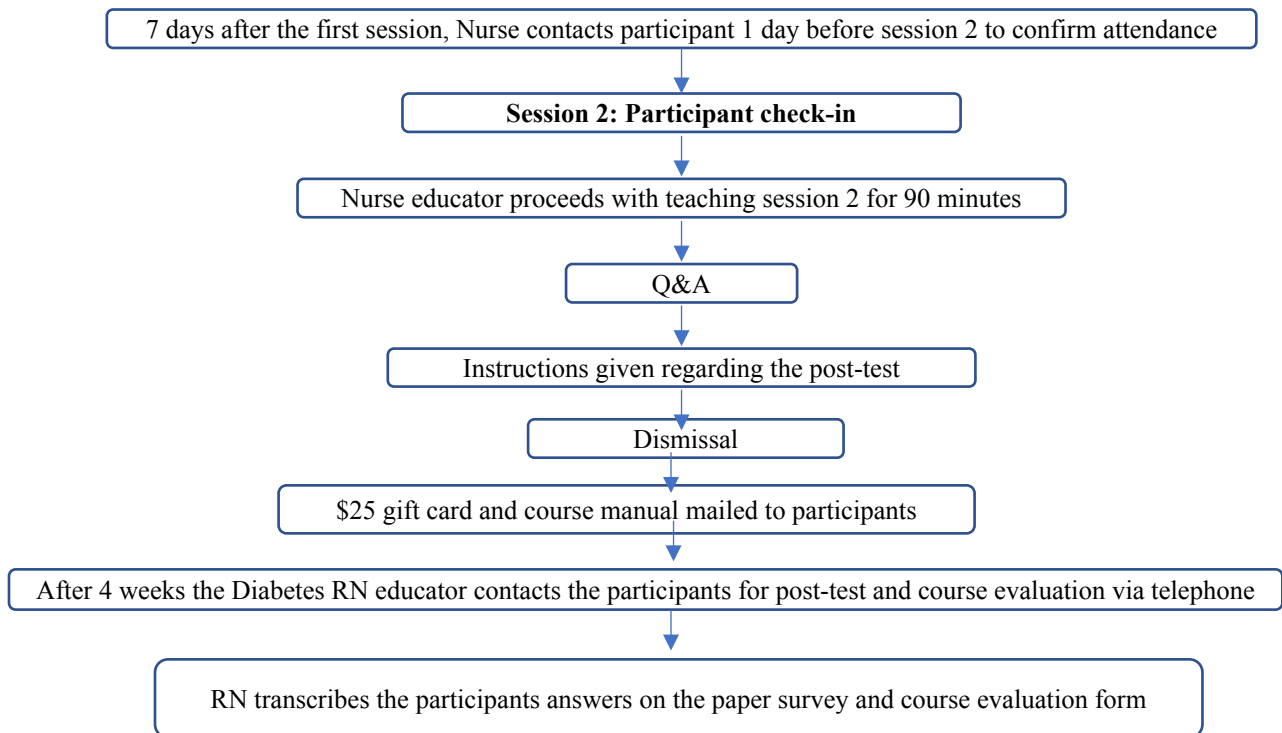
Figure 5*Intervention Flow Diagram Session 2*

Table 1*Variables and Operational Definitions*

Variable Name	Variable type and Form	Operational Definition
MATCH	Dependent Interval	Number of scores based on a 10-point Likert scale called the Motivation and Attitude Toward Changing Health (MATCH) with scores ranging from 1 (not at all confident) to 10 (totally confident) for each domain. The scores from items 1 to 9 are added to determine the motivation level.
DSES score	Dependent Interval	Number of scores based on a 10-point Likert scale called the Diabetes Self-Efficacy Scale (DSES) with scores ranging from 1 (not at all confident) to 10 (totally confident) for every domain. The scores from items 1 to 8 are added to determine the SE level.
Age	Demographic Numerical	The participants number of years from the year of birth (based on CDC report). 1= 18 to 44 years 2= 45 to 64 years 3= 65 years and older
Sex	Demographic Categorical	Assigned sex at birth 1= Male 2= Female 3= Other

Country of Birth	Demographic Categorical	Self-reported Ethnical Origin 1= Mexico (Mexican) 2= Cuba (Cuban) 3= Puerto Rico (Puerto Rican) 4= El Salvador (El Salvadorian) 5= Others
Marital Status	Demographic Categorical	Social legal status 1= Married living with family 2= Not married or Single living with family 3= Other
Educational Attainment	Demographic Categorical	Highest level of school completed by the participant 1= Elementary 2= Middle School 3= HS 4= Associate Degree 5= Bachelor's Degree 6= Graduate Degree

Table 2*Frequency Table for Nominal Variables*

Variable	<i>n</i>	%
Sex		
Male	3	30.00
Female	7	70.00
Age		
41 to 63	8	80.00
64+	2	20.00
Marital Status		
Married	7	70.00
Divorced	3	30.00
Highest Educational Level		
Elementary	7	70.00
High School	3	30.00
Race		
Hispanic	10	100.00
Language		

Spanish	10	100.00
Number of years with T2DM		
2-5 Years	3	30.00
6-9 Years	2	20.00
10+ Years	5	50.00

Table 3*Pre-Intervention MATCH and Demographics*

Variables	<i>n</i>	<i>Mean</i>	<i>SD</i>
Sex			
Male	3	4.22	0.51
Female	7	4.08	0.55
Age			
41 to 63	8	4.26	0.47
64+	2	3.56	0.16
Marital Status			
Married	7	4.21	0.49
Divorced	3	3.93	0.61
Highest Educational Level			
Elementary	7	4.03	0.60
High School	3	4.33	0.00
Race			

Hispanic	10	4.12	0.51
Language			
Spanish	10	4.12	0.51
Number of years with T2DM			
2-5 Years	3	4.44	0.19
6-9 Years	2	3.72	0.71
10+ Years	5	4.09	0.54

Table 4*Postintervention MATCH and Demographics*

Variables	<i>n</i>	<i>Mean</i>	<i>SD</i>
Sex			
Male	3	4.81	0.13
Female	7	4.67	0.43
Age			
41 to 63	8	4.67	0.39
64+	2	4.89	0.00
Marital Status			
Married	7	4.86	0.14
Divorced	3	4.37	0.53
Highest Educational Level			

Elementary	7	4.70	0.42
High School	3	4.74	0.23
Race			
Hispanic	10	4.71	0.36
Language			
Spanish	10	4.71	0.36
Number of years with T2DM			
2-5 Years	3	4.81	0.23
6-9 Years	2	4.28	0.71
10+ Years	5	4.82	0.15

Table 5*Preintervention DSES and Demographics*

Variables	<i>n</i>	<i>Mean</i>	<i>SD</i>
Sex			
Male	3	6.12	2.32
Female	7	6.79	2.16
Age			
41 to 63	8	7.38	1.45
64+	2	3.44	0.09
Marital Status			

Married	7	6.75	2.34
Divorced	3	6.21	1.73
Highest Educational Level			
Elementary	7	6.09	2.34
High School	3	7.75	0.65
Race			
Hispanic	10	6.59	2.10
Language			
Spanish	10	6.59	2.10
Number of years with T2DM			
2-5 Years	3	8.04	0.14
6-9 Years	2	5.25	0.71
10+ Years	5	6.25	2.67

Table 6*Postintervention DSES and Demographics*

Variables	<i>n</i>	<i>Mean</i>	<i>SD</i>
Sex			
Male	3	9.25	0.7
Female	7	9.48	0.5
Age			
41 to 63	8	9.58	0.45
64+	2	8.75	0.18

Marital Status			
Married	7	9.46	0.59
Divorced	3	9.29	0.47
Highest Educational Level			
Elementary	7	9.39	0.63
High School	3	9.46	0.29
Race			
Hispanic	10	9.41	0.53
Language			
Spanish	10	9.41	0.53
Number of years with T2DM			
2-5 Years	3	9.75	0.22
6-9 Years	2	9.12	0.53
10+ Years	5	9.32	0.64

Table 7

Two-Tailed Paired Samples t Test for Pre- and Postintervention

Variables	M(Pre)	SD (Pre)	M (Post)	SD (Post)	t	<i>p</i>	<i>d</i>
MATCH	4.12	0.51	4.71	0.36	-4.37	0.002	1.38
DSES	6.59	2.10	9.41	0.53	-5.31	<.001	1.68

Table 8*Pearson correlation (r)*

Pearson (r)	MATCH Mean Post-Intervention	DSES Mean Post-Intervention
MATCH Mean Pre-Intervention	0.57	N/A
DSES Mean Pre-Intervention	N/A	0.83

Appendix A

Santa Clara Valley Medical Center IRB Letter

September 13, 2021

Andrellie van Wageningen, RN, MSN, CPHQ, CNML, CNOR
Health Center Manager, VHC Milpitas
143 N. Main St. Milpitas, CA 95035

RE: Project entitled “Improving Diabetes Self-Care Motivation and Efficacy Level among Hispanic Adults with Type 2 Diabetes Mellitus at a County-Operated, Ambulatory Specialty Clinic”

At a convened meeting on September 10, 2021, the Institutional Review Board (IRB) of Santa Clara Valley Medical Center concluded that the abovementioned project does not meet the federal definition of research and is therefore not under the purview of the IRB.

Research is defined by federal regulations as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”. You may conduct the project without further submission to the IRB. If the project is modified so that the protocol meets the definition of research, the project will need to be resubmitted to the IRB for approval.

Further guidance from the IRB includes that a publication or presentation be completed on this project; it should not be indicated that the project is IRB-approved or referred to as “research”. Should you have any questions, please contact the IRB office.

Sincerely,

A digital signature block from DocuSign. It features the text "DocuSigned by:" in a small font above a blue-bordered box containing a handwritten signature in black ink that reads "Elisabeth Mailhot".

Elisabeth A. Mailhot, MD, Chair
Research and Human Subjects Review Committee

EAM/kb

Cc: Committee members

Appendix B

Motivation and Attitudes Toward Changing Health- MATCH (Spanish)

Motivación y actitudes sobre hacer Cambios a la Salud (MATCH)

INSTRUCCIONES: Estamos interesados en aprender más sobre los pensamientos y sentimientos de las personas en

cuanto a sus problemas de salud. Cuando piensa en sus problemas de salud actuales (por ejemplo: diabetes, asma, cáncer o dolor crónico), ¿en qué grado está usted de acuerdo o en desacuerdo con las siguientes afirmaciones?:

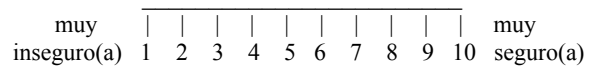
	Totalmente en Desacuerdo (1)	No estoy de Acuerdo (2)	No estoy ni de Acuerdo ni en Desacuerdo (3)	Sí estoy de Acuerdo (4)	Totalmente de Acuerdo (5)
1. Quiero encontrar una mejor manera de atender mis problemas de salud.					
2. No tengo tiempo para ocuparme de mis problemas de salud como creo que debería.					
3. Veo pocos beneficios en gastar mi tiempo y energía en controlar mis problemas de salud en estos momentos.					
4. Ahora ya estoy listo(a) para dedicarme más a manejar mejor mis problemas de salud actuales.					
5. Yo puedo acomodar en mi vida, por mí mismo(a), las tareas necesarias para manejar mis problemas de salud.					
6. El hacer esfuerzos por manejar mis problemas de salud, no da mucho resultado me trae pocos beneficios y recompensas.					
7. Estoy interesado(a) en aprender nuevas formas de manejar mejor mis problemas de salud.					
8. Realmente no vale la pena hacer todas las cosas que se me pide que haga para controlar mis problemas de salud.					
9. Yo puedo y soy capaz de hacer los cambios necesarios a mi vida para mejorar mi salud.					

Appendix C

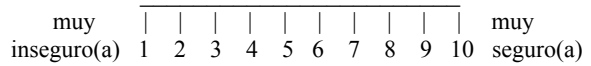
Stanford Diabetes Self-Efficacy Scale (DSES) (Spanish)

En las siguientes preguntas nos gustaría saber qué piensa Ud. de sus habilidades para controlar su enfermedad. Por favor marque el número que mejor corresponda a su nivel de seguridad de que puede realizar en este momento las siguientes tareas.

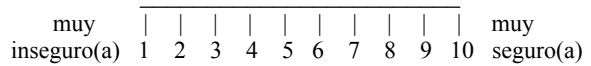
1. ¿Qué tan seguro(a) se siente Ud. de poder comer sus alimentos cada 4 ó 5 horas todos los días. Esto incluye tomar desayuno todos los días?



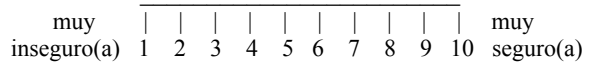
2. ¿Qué tan seguro(a) se siente Ud. de continuar su dieta cuando tiene que preparar o compartir alimentos con personas que no tienen diabetes?



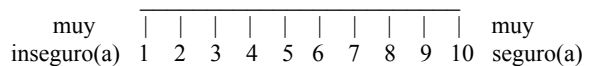
3. ¿Qué tan seguro(a) se siente Ud. de poder escoger los alimentos apropiados para comer cuando tiene hambre (por ejemplo, bocadillos)?



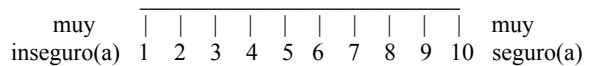
4. ¿Qué tan seguro(a) se siente Ud. de poder hacer ejercicios de 15 a 30 minutos, unas 4° 5 veces por semana?



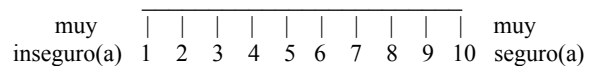
5. ¿Qué tan seguro(a) se siente Ud. de poder hacer algo para prevenir que su nivel de azúcar en la sangre disminuya cuando hace ejercicios?



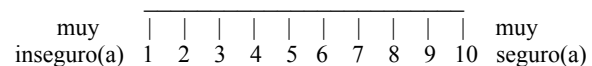
6. ¿Qué tan seguro(a) se siente Ud. de poder saber qué hacer cuando su nivel de azúcar en la sangre sube o baja más de lo normal para usted?



7. ¿Qué tan seguro(a) se siente Ud. de poder evaluar cuando los cambios en su enfermedad significan que usted debe visitar a su médico?



8. ¿Qué tan seguro(a) se siente Ud. de poder controlar su diabetes para que no interfiera con las cosas que quiere hacer?



Appendix D

Permission from MATCH Author

From: Kate Lorig

Sun, Jun 20,
8:02 PM (7
days ago)

To: Andrellie van Wagenigen

This scale is in the public domain and can be used by anyone without permission. We would appreciate it if you cited the source in any publication. As one of the authors, I also give you permission to use the scale. - Kate

Kate Lorig
Self-Management Resource Center
<https://www.selfmanagementresource.com/>
Kate@selfmanagementresource.com
650 242 8040

Appendix E
Permission from DSES Author

From: VanWageningen, Andrellie <A.VanWageningen@hhs.sccgov.org>

Sent: Thursday, April 29, 2021 1:01 PM

To: Hessler, Danielle <Danielle.Hessler@ucsf.edu>

Subject: RE: MATCH permission to use

Thank you for the quick response. I am so glad to have your permission. Was there a validity/reliability test done for the Spanish tool? I can have our Spanish translator here review it along with my Spanish Speaking DM nurse educator.

Thank you.

Andrellie

From: Hessler, Danielle <Danielle.Hessler@ucsf.edu>

Sent: Thursday, April 29, 2021 12:30 PM

To: VanWageningen, Andrellie <A.VanWageningen@hhs.sccgov.org>

Subject: [EXTERNAL] RE: MATCH permission to use

Hello,

Thank you for your interest in using the MATCH measure. You have my permission to use the measure as you describe below. I'd love to hear what you learn if you are able to share after your project!

You can find the measure in English here:

<https://behavioraldiabetes.org/scales-and-measures/#1486573022939-e501f79a-cec4>

The translation into Spanish that we recently used is attached here. I will say that some of the wording in the Spanish translation I think could be improved upon and so if your work allows for that, please do feel open to considering. Happy to answer other specific questions if/as they arise.

Warmly,

Danielle

Appendix F

Course Evaluation (Spanish)

1. Recomendaria esta clase a su familia o amigos?

Si

No

2. La maestra fue eficaz (hizo buen trabajo) en enseñarle el material?

Si

No

Comentarios adicionales sobre el curso:

Preliminary Verbal Consent (Spanish)

Guión de consentimiento telefónico para la población elegible (preliminar)

Hola, mi nombre es _____. Soy parte del personal del Departamento de Diabetes en el Centro de Especialidades de Valley. Le llamo para invitarle a participar en un estudio de investigación sobre la implementación del programa de autocontrol y educación de diabetes (DSME por sus siglas en inglés) adaptado culturalmente para adultos hispanos/latinos con Diabetes Tipo 2 no controlada y su impacto en la motivación y la autoeficacia. Su participación en este estudio es completamente voluntaria. Esto significa que no tiene que participar en este estudio a menos que lo desee.

Los objetivos del estudio son los siguientes:

- a. Promover el conocimiento sobre diabetes
- b. Capacitar a los pacientes para que realicen actividades de autocuidado de la diabetes para obtener mejores resultados de salud
- c. Eliminar las desigualdades de salud y lograr la equidad de salud entre la población latina con Diabetes Tipo 2

Este programa es gratuito y Andrellie van Wageningen, Gerente del Centro de Salud, dirigirá el estudio. El riesgo es mínimo, ya que sólo se le pedirá que asista a dos clases, de unos 90 minutos de duración. Se le pedirá que complete dos herramientas de encuesta; Puntaje de la Motivación y Actitudes hacia la Salud Cambiante (MATCH por sus siglas en inglés) y Puntaje de la Escala de Autoeficacia de Diabetes (DSES por sus siglas en inglés) antes de que comience la sesión inicial y después de que haya terminado la última sesión. Su información o identidad se guardará siempre con estricta privacidad y confidencialidad.

¿Puedo programar su asistencia a la primera y segunda sesión?

“Sí” - Gracias por su participación.

“No” - Gracias por su tiempo. Puede seguir asistiendo a las sesiones y omitir el llenar las encuestas.

Adiós.

Nombre: _____

Appendix H

FORMULARIO DE CONSENTIMIENTO INFORMADO

SANTA CLARA VALLEY MEDICAL CENTER

[Clínica para la diabetes del Valley Specialty Center]

CONSENTIMIENTO PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

TÍTULO DEL ESTUDIO DE INVESTIGACIÓN: Mejorando el nivel de eficacia y de motivación del cuidado personal de la diabetes entre adultos latinos con diabetes mellitus tipo 2 no controlada en una clínica especializada ambulatoria operada por el condado.

RESUMEN

El objetivo de este proyecto de mejora de la calidad es ver si la educación sobre el cuidado personal de la diabetes (diabetes self-management education, DSME) dirigida específicamente a la población hispano-latina puede mejorar la motivación y la confianza de una persona en el autocuidado de la diabetes. Si decide participar en este estudio, se le pedirá que asista a dos clases en grupo. Ambas clases serán dadas por personal de enfermería educador en diabetes, el personal es hispanohablante y la información será específica de la cultura latina/hispana. La participación en este estudio es voluntaria.

Si participa, recibirá una llamada de recordatorio del personal de la clínica de diabetes uno o dos días antes de la fecha programada de las sesiones. También se le pedirá que regrese a la Clínica de Diabetes del Valley Specialty Center dentro de cuatro semanas para asistir a la segunda sesión. También se le pedirá que complete dos encuestas para saber si la clase lo ayuda con sus niveles de motivación y confianza. Su participación total en el estudio es de unos 4 meses. Asistirá a dos clases en línea, completará dos encuestas antes de que comience la primera clase en línea y tres meses después de la segunda clase en línea. La segunda clase está programada cuatro semanas después de la primera.

Algunos riesgos para el estudio incluyen aburrimiento, fatiga mental, vergüenza por un rendimiento deficiente o frustración. Porque esta es una clase en línea (por computador) su confidencialidad no está totalmente garantizada. Los posibles beneficios pueden ser un aumento de sus conocimientos sobre la diabetes, su motivación y su confianza para realizar actividades de cuidado personal. También puede disminuir su nivel de A1C, su peso y mejorar otras pruebas de laboratorio.

Si está interesado en obtener más información sobre el proyecto de mejora de la calidad, siga leyendo la información que se proporciona a continuación.

PATROCINADOR DEL ESTUDIO: No hay patrocinador para este estudio.

INVITACIÓN A PARTICIPAR: Lo invitamos a participar en este proyecto de mejora de la calidad. La siguiente información se proporciona para ayudarlo a tomar una decisión informada acerca de si debe participar o no.

LEA ESTE FORMULARIO DE CONSENTIMIENTO DETENIDAMENTE. Si tiene alguna pregunta, no dude en preguntar.

Antes de aceptar participar en este estudio de investigación, es importante que lea y comprenda la información contenida en este formulario de consentimiento. Este proceso se denomina consentimiento informado.

Este formulario de consentimiento describe el propósito, los procedimientos, los beneficios, los riesgos, las molestias y las precauciones que deben tomarse durante el estudio. También describe su derecho a retirarse del estudio en cualquier momento y las alternativas disponibles.

Este formulario de consentimiento puede contener palabras que no entienda. Pida a su gerente de atención para la diabetes o a un miembro del personal del proyecto que le explique cualquier palabra o información que no entienda con claridad.

¿POR QUÉ HA SIDO SELECCIONADO PARA PARTICIPAR? Se le ha seleccionado para participar porque es un adulto hispano/latino con diabetes mellitus tipo 2 (DMT2) no controlada (>9 % Hgb A1C).

¿POR QUÉ SE ESTÁ REALIZANDO ESTE ESTUDIO? El objetivo del proyecto es ayudar a los pacientes a mejorar su nivel de motivación y su capacidad para realizar actividades de cuidado personal en torno a su diabetes tipo 2. A través de este programa, recibirá talleres educativos gratuitos, adaptados a su cultura hispana/latina. Este proyecto puede ayudarlo a mejorar sus conocimientos sobre la diabetes, capacitarlo para participar en su propia atención y evitar complicaciones de la diabetes que afecten sus resultados de salud y a su calidad de vida.

¿QUÉ IMPLICA EL ESTUDIO? Este proyecto tardará 16 semanas en completarse. El investigador principal recopilará información de salud importante de la historia clínica electrónica, como su nivel reciente de Hgb A1C, índice de masa corporal (IMC). También se obtendrá información sobre usted que incluirá el número de registro médico (medical record number, MRN), edad, sexo, número de años con DMT2 estado civil, país de nacimiento, mayor nivel educativo y preferencia de idioma. Se necesitarán su dirección, correo electrónico y número de teléfono para comunicarse con usted antes, durante y después de completar las dos sesiones.

Antes de que comience el proceso en línea (por computadora), recibirá una llamada del miembro del personal del proyecto para que podamos ayudarlo a prepararse para asistir a las clases. Estas instrucciones incluirán cómo configurar un correo electrónico, descargar y usar Microsoft (MS) Teams y DocuSign. También recibirá una copia electrónica del consentimiento informado y de las dos encuestas a través de una dirección de correo electrónico segura. Después de que revise y firme el consentimiento informado, nos lo devolverá utilizando su correo electrónico. También podemos enviarle el consentimiento informado y las encuestas a su dirección postal. Adjuntaremos un sobre que ya tiene nuestra dirección y el sello postal. Recibirá una llamada telefónica uno o dos días antes de la fecha

programada de la clase para confirmar su inscripción. Los siguientes resúmenes de las dos clases:

La CLASE núm. 1 durará unos 90 minutos. Los participantes se unirán a la clase en línea (por computadora) 15 minutos antes del inicio de la clase. Antes de que el personal de enfermería hispanohablante (bilingüe) educador en diabetes comience a impartir la enseñanza, se le informará sobre sus derechos y las normas de privacidad/confidencialidad. Un miembro del personal del proyecto lo ayudará si tiene algún problema.

El personal de enfermería hispanohablante (bilingüe) educador en diabetes impartirá la primera sesión utilizando Microsoft PowerPoint. La primera sesión incluirá los siguientes temas: Aspectos básicos de la DMT2 y resumen del DSME, estándares de atención actuales del DSME según la Asociación Americana de Diabetes (American Diabetes Association, ADA) y los cinco primeros conceptos de los 7 comportamientos de cuidado personal de según la Asociación de Especialistas en Atención y Educación en Diabetes (Association of Diabetes Care & Education Specialists, ADCES). Estos comportamientos abarcan la toma de medicamentos, el monitoreo del azúcar en sangre, la resolución de problemas, el manejo de la salud y la reducción de riesgos. Asistirá a la segunda clase virtual cuatro semanas después, para asistir a la sesión final (la clase 2 a continuación).

El contenido del curso de ambas sesiones se basa en los 7 comportamientos de cuidado personal de según la ADCES y estándares de atención actuales del DSME según la Asociación Americana de Diabetes (ADA).

La CLASE núm. 2 durará unos 90 minutos. No necesita firmar otro consentimiento informado, pero tendrá que continuar con el proceso de inicio de sesión habitual.

El educador hispanohablante (bilingüe) en diabetes enseñará la segunda/última sesión utilizando Microsoft PowerPoint basándose en los 7 comportamientos de cuidado personal de según la ADCES. Esta sesión incluirá los siguientes temas: Alimentación saludable y actividad física.

Al finalizar la segunda sesión, personal de enfermería hispanohablante (bilingüe) educador en diabetes le pedirá que rellene un formulario de evaluación del curso.

DESPUÉS DE LA INTERVENCIÓN:

A los 3 meses de la primera clase se necesitarán unos 15 a 20 minutos. Se le pedirá que realice las encuestas posteriores a la intervención por teléfono. El personal de enfermería hispanohablante (bilingüe) educador en diabetes intentará hasta tres veces. Si no es posible comunicarse con el participante, se le excluirá del estudio.

¿CUÁLES SON LOS RIESGOS O LAS POSIBLES MOLESTIAS DEL ESTUDIO? A continuación, se presentan los riesgos y molestias graves frecuentes que podría tener durante este estudio.

El aburrimiento, la fatiga mental, la vergüenza por un rendimiento deficiente o la frustración son riesgos menores pero frecuentes. No podemos garantizar que su confidencialidad esté completamente protegida en el entorno de un aula grupal en línea.

¿HAY BENEFICIOS POSIBLES PARA LAS PERSONAS QUE PARTICIPAN EN EL ESTUDIO? Los datos indican que los programas educativos y de autogestión de la diabetes adaptados culturalmente pueden ser eficaces para controlar la DMT2. Se desconoce si esta intervención es más eficaz que otras. **POR LO TANTO, NO PODEMOS GARANTIZAR NI PROMETER QUE USTED VAYA A RECIBIR NINGÚN BENEFICIO POR PARTICIPAR EN ESTE ESTUDIO.**

¿HAY BENEFICIOS POSIBLES PARA LA SOCIEDAD A PARTIR DE ESTE ESTUDIO? La información obtenida de este proyecto puede ayudar a futuros pacientes con diabetes mellitus tipo 2 no controlada.

¿QUÉ ALTERNATIVAS EXISTEN A LA PARTICIPACIÓN EN ESTE ESTUDIO? La alternativa es excluirse del proceso de recopilación de datos, pero seguir asistiendo a las sesiones en línea.

¿SE MANTENDRÁ LA CONFIDENCIALIDAD DE MI INFORMACIÓN? Cualquier información obtenida durante este estudio que pueda identificarlo se mantendrá tan confidencial como sea posible según la ley. Los representantes de la Oficina para la Protección de Seres Humanos en Estudios de Investigación (Office for Human Research Protections, OHRP) o la Administración de Alimentos y Medicamentos (Food and Drug Administration, FDA) pueden inspeccionar sus registros durante las auditorías de investigación. Sus registros médicos, que lo identifican a usted y el formulario de consentimiento firmado por usted, también pueden ser inspeccionados por el Comité de Revisión de Investigaciones y Sujetos Humanos del Santa Clara Valley Medical Center, y por las personas responsables de la auditoría financiera y la facturación. Debido a la necesidad de revelar información a estas partes, no se puede garantizar la confidencialidad absoluta.

La información obtenida en este estudio puede ser publicada en revistas científicas o presentada en reuniones científicas, pero su nombre no será revelado.

¿HAY ALGÚN COSTO PARA MÍ? La participación en este estudio no tiene ningún costo para usted.

¿RECIBIRÉ ALGUNA COMPENSACIÓN POR PARTICIPAR? No se le pagará por participar en este estudio. Sin embargo, como incentivo, los participantes recibirán una tarjeta regalo de \$25 de un supermercado seleccionado después de asistir a la primera sesión en línea y otra tarjeta regalo de \$25 de un supermercado seleccionado después de completar la segunda sesión en línea.

¿A QUIÉN DEBO CONTACTAR SI TENGO UNA EMERGENCIA RELACIONADA CON LA INVESTIGACIÓN? Esta investigación conlleva riesgos mínimos. Sin embargo, si desea hablar con alguien después de sus clases o cree que tiene una emergencia relacionada con la investigación, póngase en contacto con cualquier miembro del personal de mejora de la calidad en este número (408) 957-8678 o (408) 793-2515 durante el horario laboral (de lunes a viernes). Para cualquier otra preocupación de emergencia médica, incluida la angustia emocional o mental, deberá llamar o llamar al 911.

¿PUEDO NEGARME A PARTICIPAR O DEJAR DE PARTICIPAR? Es libre de decidir no participar en este estudio o retirarse en cualquier momento sin que ello afecte negativamente a su relación con su(s) médico(s), gerente(s) de atención de la diabetes o un miembro(s) del personal del estudio o del Santa Clara Valley Medical Center, de la Clínica de Diabetes del Valley Specialty Center o cualquier departamento del Santa Clara Valley Health and Hospital System (SCVHHS). La decisión de no participar no hará que pierda ninguno de los beneficios asociados con su atención de la salud.

¿QUÉ PASA SI SE DISPONE DE NUEVA INFORMACIÓN? Si durante el curso de este estudio se desarrolla alguna información o se producen cambios que puedan afectar a su disposición para seguir participando, se le informará inmediatamente.

¿PUEDEN RETIRARME DEL ESTUDIO? Usted puede ser retirado del estudio sin su consentimiento por cualquiera de las siguientes razones:

- Su o sus proveedores de atención médica deciden que continuar en el estudio podría serle perjudicial.
- Queda embarazada,
- No sigue los procedimientos del estudio.

¿SE UTILIZARÁN MIS DATOS O ESPECÍMENES OBTENIDOS EN ESTE ESTUDIO EN FUTURAS INVESTIGACIONES? Su información privada no se utilizará para investigaciones futuras.

¿SE UTILIZARÁ MI MUESTRA BIOLÓGICA O TEJIDO PARA PRUEBAS GENÉTICAS? No corresponde.

¿QUIÉN TENDRÁ ACCESO A LOS RESULTADOS DEL ESTUDIO? El investigador principal y el personal del proyecto son los únicos que tendrán acceso a los resultados del estudio.

¿TENDRÉ ACCESO A LOS RESULTADOS DEL ESTUDIO? Los investigadores principales del estudio esperan que se publiquen los resultados del estudio cuando esté completo, pero esto no está garantizado. En ninguna publicación se incluirá información que lo identifique.

¿A QUIÉN LLAMO SI TENGO ALGUNA PREGUNTA? Si tiene alguna pregunta, no dude en preguntar y se le responderá en ese momento. Si se le ocurre alguna otra pregunta más adelante, no dude en comunicarse con uno de los investigadores principales o con un miembro del personal del proyecto en uno de los números de teléfono que figuran al final de este formulario de consentimiento. El Comité de Revisión de Investigaciones y Sujetos Humanos del Santa Clara Valley Medical Center ha revisado este estudio y revisará cualquier preocupación o queja que usted pueda tener con respecto a su participación en el estudio o preguntas que pueda tener sobre sus derechos como participante de la investigación. Se trata de un comité que se ocupa de proteger a las personas que se ofrecen voluntariamente a participar en estudios de investigación. Se puede contactar con el comité llamando a la oficina de 9:00 a.m. a 5:00 p.m., de lunes a viernes al 408/885-2383 o escribiendo a Research Committee, Santa Clara Valley Medical Center, Institutional Review Board Office, 777 Turner Dr. Office 2N106 San Jose, California 95128.

DOCUMENTACIÓN DEL CONSENTIMIENTO INFORMADO: Usted está tomando voluntariamente la decisión de participar o no en este estudio de investigación. Si desea participar, rellene las líneas a continuación. Su firma certifica que el contenido y el significado de la información contenida en este formulario de consentimiento le ha sido explicado en su totalidad y que ha decidido participar habiendo leído y comprendido la información presentada. Guarde la copia del formulario de consentimiento que se le entregue para que tenga esta información. Gracias por su interés en este estudio.

Nombre del sujeto (en letra de molde)

Número de registro médico del sujeto

Firma del sujeto

Fecha de la firma

A mi juicio, el sujeto está dando voluntariamente y a sabiendas su consentimiento informado y posee la capacidad legal para dar su consentimiento informado para participar en este estudio de investigación.

Nombre en letra de molde y firma del investigador/designado

Fecha de la firma

IDENTIFICACIÓN DEL EQUIPO DEL PROYECTO DE MEJORA DE LA CALIDAD

Investigador principal: Andrellie van Wageningen, RN, MSN, CPHQ, CNML, CNOR
Gerente del Milpitas Health Center, Valley Health Center
43 N. Main St., Milpitas, CA, 95035
Número de teléfono: (408) 957-8678

Personal del proyecto: Laura Camberos-Medina, RN, MS
Gerente asistente de enfermería de la Clínica de Diabetes del Valley Specialty Center
751 S. Bascom Ave. San Jose, CA 95128
Número de teléfono: (408) 793-2515

Michelle Teron, RN
Coordinadora de enfermería para la diabetes, Valley Specialty Center
751 S. Bascom Ave. San Jose, CA 95128
Número de teléfono: (408) 793-2515

Appendix I

Q&A Pop Quiz Items (Spanish)

Basic Diabetes Education Questions

1. True or false:
Diabetes is a sugar problem
2. True or false:
Hyperglycemia is low blood sugar
3. True or false:
Hypoglycemia is low blood sugar
4. What is the recommended HbA1c?
5. True or false:
High blood sugar increases risks for complications
6. True or false:
Hyperglycemia is blood sugar level > than 250 mg/dl
7. True or false:
Hypoglycemia is blood sugar level > than 250 mg/dl

Prevention of Long-term Complications

1. True or false:
Only type 1 diabetes is at risk of developing long-term complications
2. True or false:
Reaching target blood glucose, blood pressure and lipid levels slows the progress of retinopathy?
3. True or false:
Heart damage occurs when large vessels are affected
4. True or false:
You can prevent and lower your risk for heart problems by eliminating preventable risk factors

Nutrition Review

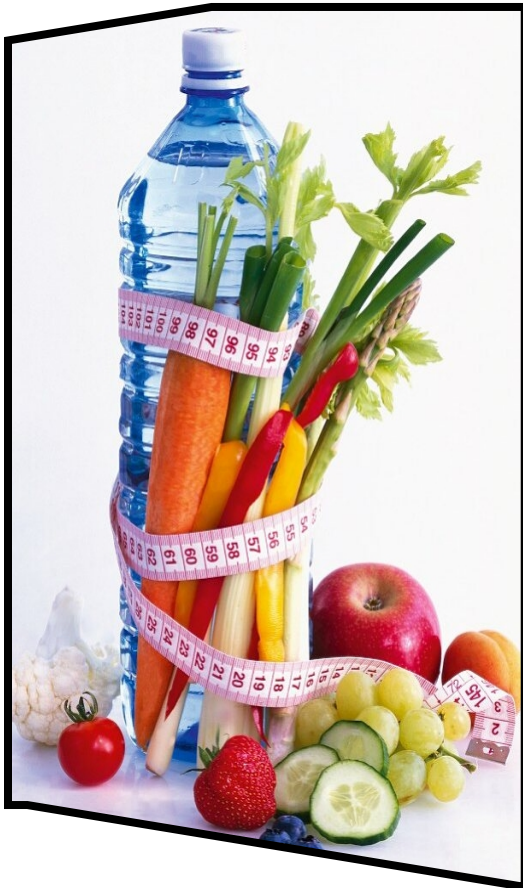
1. Prediabetes is diagnosed by an A1C of 5.7-6.4% and Diabetes is diagnosed by an A1C of 6.5% and above.
2. Consuming a well-balanced diet in combination with exercise can be an effective way to prevent and treat type 2 diabetes.
3. Carbohydrates are the foods that cause blood sugars to increase – Milk and milk products, fruits and juices/regular soda, starches/grains/breads, and sweets.
4. Men can consume 4 portions of carbs per meal and women can consume 3 portions of carbs per meal.

Appendix J

DSME Course Manual (Spanish)



Manual educativo para pacientes con diabetes



Appendix K

PowerPoint Presentation DSME Class (Spanish)



Appendix L

Culturally Tailored DSME Programme Course Curriculum

Learning Objectives - At the end of the session, the participant will be able to:

- Manage their diabetes at home.
- Discuss Diabetes, how it affects the body and treatment options.
- Discuss their medication usage, storage and demonstrate proper intake/administration of medication.

Topics Content (Tailored for the Target Population) Available in English and Spanish
Diabetes Education, Oral Medications, and Incretin Mimetics (60 Min)

- Overview of Diabetes
- Importance of DM education
- Insulin and Glucose
- BG check missed dose and sick day rules.
- Exercise Plan

Oral Medications and Incretin mimetics

- Definition of oral medications, side effects, hypoglycemia
- Types of oral medications
 1. Biguanides
 2. Sulfonylureas
 3. Meglitinides
 4. SGLT-2 inhibitor
 5. DPP-4 inhibitors
 6. Thiazolidinediones
 7. Alpha glucosidase inhibitors
 8. Types of injectables and oral-incretin mimetics (GLP-1)

Methods of Instruction (Oral Medications and Incretin Mimetics)

- **Visuals** provided of examples of diabetes medicines.
- **Video presentation**
- **Handouts** (one per participant)
 1. Examples of diabetes medicines
 2. Treatment of low blood glucose
 3. Medicine list

Additional items:

1. Sample pill bottle
2. Medication assistance programs
3. Pill boxes

4. GLP1 pen devices

Methods of evaluation (oral medications and incretin mimetics)

Knowledge will be evaluated by achievement of learning objectives and by responses to questions during the session. The ability to apply knowledge will be evaluated by the appropriate use of medicines and through the achievement of program outcome measures.

Learning Objectives – At the end of the session, the participant will be able to:

- Demonstrate and describe ways to prevent, detect and treat acute complications, including hypoglycemia, hyperglycemia, diabetes ketoacidosis, sick day guidelines, and severe weather or situation crisis and diabetes supply management.
- Demonstrate and describe ways to prevent, detect and treat chronic complications, including immunizations and preventive eye, foot, dental, and renal examinations, as discussed in this learning class.
- Discuss healthy coping with psychosocial issues and concerns.

Topics Content (Tailored for the Target Population) Available in English and Spanish

Prevention of long-term complications (45 min)

- Diabetic retinopathy
- The heart and blood vessels
- Heart attack
- Stroke
- Kidney Disease
- Nerve disease
- Foot problems

Learning Objectives – At the end of the session, the participant will be able to

- Understand/follow basic diabetes meal planning
- Understand/describe food groups that affect blood sugar

Topics Content (Tailored for the Target Population) Available in English and Spanish

Basic Nutrition Education (30 Minutes)

- Foods that affect blood sugar
- How to count carbs
- Meal Planning

The methods of instructions for diabetes education, prevention of complications and basic nutrition topics are as follows:

- Power point presentation
- Diabetes Education Booklet
- Discussion

Methods of evaluation for diabetes education, prevention of complications and basic nutrition topics are as follows:

- Q &A (included in the Power point slides)

Appendix M

AADE 7 Self-Care Behaviors



Introduction

The American Association of Diabetes Educators (AADE) has defined the AADE 7 Self-Care Behaviors™ as a framework for patient-centered diabetes self-management education and training (DSME/T) and care. The seven self-care behaviors essential for successful and effective diabetes self-management are *healthy eating, being active, monitoring, taking medication, problem solving, healthy coping, and reducing risks*.¹⁻⁹ AADE 7 Self-Care Behaviors™ (AADE7™) provides an evidenced-based framework for assessment, intervention and outcome (evaluation) measurement of the diabetes patient, program, and population.¹⁰⁻¹² In addition, diabetes educator interventions can be organized according to the framework. This position statement describes the application of the AADE 7 Self-Care Behaviors™ framework in diabetes education and care; it also explores widespread extension to other chronic diseases and wellness.

Appendix N

Preliminary verbal consent (English)

Telephone Consent Script for Eligible Population (Prelim)

Hello, my name is _____. I am a staff member from VSC Diabetes Center. I am calling to invite you to participate in a research study about the implementation of the culturally tailored diabetes self-management and education (DSME) program among Hispanic/Latino adults with uncontrolled T2DM and its impact on motivation and self-efficacy. Your participation in this study is completely voluntary. This means that you do not have to participate in this study unless you want to.

The purposes of the study include the following:

- a. Promote diabetes knowledge
- b. Empowering patients to perform diabetes self-care activities for better health outcomes
- c. Eliminate health disparities and achieve health equity among the Latinx population with T2DM

This is free of cost, and Andrellie van Wageningen, HCM will be leading the study. There is very minimal risk involved, as you will only be asked to attend two classes, lasting for approximately 90 minutes. You will be asked to complete two survey tools (MATCH and DSES) before the initial session begins and after the last session has ended. Your information or identity will always be guarded with strict privacy and confidentiality.

May I go ahead and schedule you to attend the first and second sessions?

“Yes” - Thank you for your participation.

“No”- Thank you for your time. You may still attend the sessions and skip filling out the surveys.

Bye.

Name: _____

Appendix O

Informed Consent

SANTA CLARA VALLEY MEDICAL CENTER

[Valley Specialty Center – Diabetes Clinic]

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF THE RESEARCH STUDY: Improving Self-Care Motivation and Efficacy Level among Latinx Adults with Type 2 Diabetes Mellitus at a County-Operated, Ambulatory Specialty Clinic.

CONCISE SUMMARY

The purpose of this study is to test whether culturally tailored diabetes self-management education (DSME) can improve an individual's motivation and confidence level in performing self-care activities. If you choose to take part in this study, you will be asked to attend two group classes. Both classes will be taught by a Spanish-speaking Diabetes Nurse Educator and the information will be specific to the Latino/Hispanic culture. Participating in this study is voluntary. If you participate, you will be receiving a reminder call from the diabetes clinic staff one or two days before the scheduled date of the sessions. You will also be asked to return to Valley Specialty Center-Diabetes Clinic in four-weeks to attend the second session. You will also be asked to complete two surveys to know if the class is helping your motivation level and confidence. Your total study time involvement is about 4 months. Some risks to the study include boredom, mental fatigue, embarrassment at poor performance, or frustration. Possible benefits may be an increase in your diabetes knowledge, motivation, and confidence to do self-care activities. It may also decrease your A1c level, weight, and other lab work.

STUDY SPONSOR: There is no sponsor for this study.

INVITATION TO PARTICIPATE: You are invited to participate in this research study. The following information is provided to help you make an informed decision about whether to participate.

PLEASE READ THIS CONSENT FORM CAREFULLY. If you have any questions, please do not hesitate to ask.

Before agreeing to participate in this research study, it is important that you read and understand the information contained in this consent form. This process is called informed consent.

This consent form describes the purpose, procedures, benefits, risks, discomforts, and precautions that should be taken during the study. It also describes your right to withdraw from the study at any time and available alternatives.

This consent form may contain words that you do not understand. Please ask the study doctor or a member of the study staff to explain any words or information that you do not clearly understand.

WHY HAVE YOU BEEN SELECTED TO PARTICIPATE? You have been selected to participate because you are an adult, Hispanic/Latino with uncontrolled Type 2 Diabetes Mellitus (T2DM) (>9% Hgb A1c).

WHY IS THIS STUDY BEING DONE? The purpose of the project is to help patients improve their motivation level and their ability to perform self-care activities around their Type 2 diabetes. Through this program, you will receive free educational workshops that are tailored to your Hispanic/Latino culture. This project may help improve your diabetes knowledge, empower you to participate in your own care, and avoid diabetes complications that impact your health outcomes and quality of life.

WHAT IS INVOLVED IN THE STUDY? This study will take 16 weeks to complete. The principal investigator will gather important health information from the electronic health record, such as your recent Hgb A1c level and body mass index (BMI). Information about you will also be taken, which includes name, age, sex, MRN, number of years with T2DM, marital status, country of birth, highest educational attainment, and language preference. Your mailing address, e-mail address, and telephone number will be needed to communicate with you before, during, and after you completed the two sessions.

You will be asked to return to the clinic only twice. The following summaries of the 2 visits:

VISIT 1 will last approximately 90 minutes. Patients are checked 15 minutes prior to the start of the class. Informed consent will be obtained, and you will be briefed regarding your rights and privacy/confidentiality rules. You will also be asked which paper format of the surveys (e.g., English or Spanish) they prefer to fill out for the preintervention data collection. The bilingual diabetes RN educator will be available to give instructions on filling out the selected survey. The Spanish-speaking (bilingual) diabetes nurse educator will teach the first session using Microsoft PowerPoint. Both sessions' course content is based on the ADCES' 7 Self-Care Behaviors (Appendix I) and American Diabetes Association DSME standards of care. The first session will include the following topics: T2DM basics and DSME overview, current ADA DSME standards of care, and the first five concepts of ADCES 7 Self-care behaviors. These behaviors include taking medications, monitoring blood sugar, problem solving, health coping, and reducing risks.

You will return after four weeks to attend the final session (visit 2 below).

VISIT 2 will last approximately 90 minutes. You do not need to sign another informed consent, but you will have to proceed with the usual check-in process.

The Spanish-speaking (bilingual) diabetes RN educator will teach the second or final session using Microsoft PowerPoint based on the ADCES' 7 Self-Care Behaviors. This session will include the following topics: Healthy eating and being active.

At the conclusion of the second session, the Spanish-speaking (bilingual) diabetes RN educator will ask you to fill out a course evaluation form.

POST INTERVENTION:

Three months after your first class will require approximately 15-20 minutes. You will be asked to complete the postintervention surveys via the telephone. The Spanish-speaking (bilingual) diabetes nurse educator will attempt up to three times. Failure to contact the participant will result in exclusion from the study.

WHAT ARE THE RISKS AND/OR POTENTIAL DISCOMFORTS OF THE STUDY?

Below are both the serious and common risks and discomforts you could potentially experience during this study: Boredom, mental fatigue, embarrassment at poor performance, or frustration are minor but common risks.

ARE THERE POTENTIAL BENEFITS TO PEOPLE PARTICIPATING IN THE STUDY? Data indicate that culturally tailored diabetes self-management and education programs may be effective in controlling T2DM. It is not known whether this intervention is more effective than others. **THEREFORE, WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS BY PARTICIPATING IN THIS STUDY.**

ARE THERE POTENTIAL BENEFITS TO SOCIETY FROM THIS STUDY? The information obtained from this study may help future patients who have uncontrolled Type 2 Diabetes Mellitus.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATING IN THIS STUDY? The alternative is to opt out to participate in the data collection process but attend the sessions.

WILL MY INFORMATION BE KEPT CONFIDENTIAL? Any information obtained during this study that could identify you will be kept as confidential as is possible within the law. Representatives of the Office for Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA) may inspect your records during research audits. Your medical records that identify you and the consent form signed by you may also be inspected by the Research and Human Subjects Review Committee of Santa Valley Medical Center for financial auditing and billing. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

The information obtained in this study may be published in scientific journals or presented at scientific meetings, but your name will not be revealed.

ARE THERE ANY COSTS FOR ME? There is no charge to you for participating in this study.

WILL I RECEIVE ANY COMPENSATION FOR PARTICIPATING? There is no payment provided for participation in this study.

WHOM SHOULD I CONTACT IF I HAVE A RESEARCH RELATED EMERGENCY? This investigation comes with minimal risks. However, if you would like to speak to someone following your classes or feel you have an emergency related to the research, please contact any of the study staff at this number (408) 957-8674 or (408) 793-2515 during business hours (Monday to Friday).

CAN I DECLINE TO PARTICIPATE OR WITHDRAW FROM PARTICIPATING? You are free to decide not to participate in this study or to withdraw at any time without adversely affecting your relationship with your physician(s), the study doctor or study staff, or Santa Clara Valley Medical Center, Valley Specialty Center- Diabetes Clinic, or any department in the Santa

Clara Valley Health and Hospital System (SCVHHS). Deciding not to participate will not cause you to lose any of the benefits associated with your health care.

WHAT IF NEW INFORMATION BECOMES AVAILABLE? If any information develops or changes occur during this study that may affect your willingness to continue participating, you will be informed immediately.

CAN I BE TERMINATED FROM THE STUDY? You may be removed from the study without your consent for any of the following reasons:

- The study doctors decide that continuing in the study would be harmful to you.
- You become pregnant,
- You fail to follow the study procedures.

WILL MY DATA OR SPECIMENS COLLECTED IN THIS STUDY BE USED IN FUTURE RESEARCH? Your private information will not be used for future research.

WILL MY BIOSPECIMEN OR TISSUE BE USED FOR GENETIC TESTING? Not applicable

WHO WILL HAVE ACCESS TO RESULTS FROM THE STUDY? The PI and study personnel will have access to the results of the study. San Jose State University will have access the findings of the study, but no information will be shared to this institution that will identify you.

WILL I HAVE ACCESS TO THE RESULTS OF THE STUDY? The study PI anticipates publishing the results of the study when it is complete, but this is not guaranteed. No identifying information will be included in any publications.

WHOM DO I CALL IF I HAVE ANY QUESTIONS? If you have any questions, please do not hesitate to ask, and they will be answered at this time. If you think of any additional questions later, please feel free to contact the primary investigator and/or study personnel at one of the telephone numbers listed at the bottom of this consent form. The Research and Human Subjects Review Committee of Santa Clara Valley Medical Center has reviewed this study and will review any concerns or complaints you may have regarding your participation in the study or questions you may have about your rights as a research subject. This committee is concerned with protecting people who volunteer to participate in research studies. The Committee may be reached by calling the office from 9:00 a.m. to 5:00 p.m., Monday through Friday at 408/885-2383 or by writing to the Research Committee, Santa Clara Valley Medical Center, Institutional Review Board Office, 777 Turner Dr. Office 2N106 San Jose, California 95128.

DOCUMENTATION OF INFORMED CONSENT: You are voluntarily making a decision whether to participate in this research study. If you would like to participate, please fill in the lines below. Your signature certifies that the content and meaning of the information on this consent form have been fully explained to you and that you have decided to participate having read and understood the information presented. Keep the copy of the consent form that you are given so that you have this information. Thank you for your interest in this study.

Subject Name (Printed)

Subject Medical Record Number

Signature of Subject

Date Signed

In my judgment, the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Printed Name and Signature of Investigator/Designee

Date Signed

IDENTIFICATION OF STUDY INVESTIGATORS

Principal Investigator: Andrellie van Wageningen, RN, MSN, CPHQ, CNML, CNOR
Valley Health Center – Milpitas Health Center Manager
143 N. Main St., Milpitas CA, 95035
Tel. No: (408) 957-8674

Study Personnel: Laura Camberos-Medina, RN,
Valley Specialty Center – Diabetes Clinic Assistant Nurse Manager
751 S. Bascom Ave. San Jose, CA 95128
Tel. No: (408) 793-2515

Michelle Teron, RN
Valley Specialty Center – Diabetes Nurse Coordinator
751 S. Bascom Ave. San Jose, CA 95128
Tel. No: (408) 793-2515

24 Hour Emergency Contact Information: If you experience an injury or adverse effect that you feel requires urgent medical attention, call 911 or go to the nearest emergency room or urgent care clinic. Tell the staff in the emergency room or clinic that you are participating in a research study and that they should immediately telephone one of the study personnel at this number (408) 957-8674 or (408) 793-2515 during business hours (Monday to Friday).

Appendix P

Motivation and Attitude Toward Changing Health (MATCH-English)

Directions: We are interested in learning more about people’s thoughts and feelings about their health problems. How much do you agree or disagree with the following statements when thinking about your current health problems (e.g., diabetes)?

	Strongly Disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly Agree (5)
1. I want to find a better way to take care of my health problems.					
2. I don’t have time to take care of my health problems the way I think I should.					
3. I see few benefits putting time and energy into managing my health problems now.					
4. I am ready to do more to better manage my health problems now.					
5. I am able to fit the tasks of managing my health problems into my life.					
6. Working to manage my health problems has little pay off or benefit.					
7. I am interested in finding new ways to better manage my health problems.					
8. It is not truly worth it to do all the things that I am asked to do to manage my health problems.					
9. I am able to make the changes in my life that are needed to improve my health.					

SCORING for the MATCH:

WILLINGNESS: Calculate the mean/average of items 1, 4, and 7.

ABLE: Calculate the mean/average of items 5, 9, 2 (Item 2: REVERSE SCORED)

Note: Reverse scored item (5=1, 4=2, 3=3, 2=4, 1=5)

WORTHWHILE: Calculate the mean/average of items: 3, 6, 8 (all three items REVERSE SCORED*)

Note: Reverse scored item (5=1, 4=2, 3=3, 2=4, 1=5)

TOTAL SCALE: Calculate the mean/average of Willingness, Able, and Worthwhile

Note regarding missing data: Calculate based on available data if 66% or greater responses are available for a given subscale (i.e., two of the three items). A subscale is missing data if only one of the three items has available data. A total scale is missing data if any subscale is missing.

MATCH 5.8.19 © Behavioral Diabetes Institute

Appendix P

Stanford Diabetes Self-Efficacy Scale (DSES) and Score Interpretation (English)

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

not at all confident		totally confident
	1 2 3 4 5 6 7 8 9 10	

2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

not at all confident		totally confident
	1 2 3 4 5 6 7 8 9 10	

3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?

not at all confident		totally confident
	1 2 3 4 5 6 7 8 9 10	

4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

not at all confident		totally confident
	1 2 3 4 5 6 7 8 9 10	

5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

not at all confident		totally confident
	1 2 3 4 5 6 7 8 9 10	

- 6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

not at all											totally
confident	1	2	3	4	5	6	7	8	9	10	confident

- 7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

not at all											totally
confident	1	2	3	4	5	6	7	8	9	10	confident

- 8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

not at all											totally
confident	1	2	3	4	5	6	7	8	9	10	confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the eight items. If more than two items are missing, do not score the scale. A higher number indicates higher self-efficacy.

Characteristics

Tested on 186 subjects with diabetes.

No. of items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
8	1-10	6.87	1.76	.828	NA

Source of Psychometric Data

Stanford English Diabetes Self-Management study. Study reported in Lorig K, Ritter PL, Villa FJ, Armas J. Community-Based Peer-Led Diabetes Self-Management: A Randomized Trial. The Diabetes Educator 2009; Jul-Aug;35(4):641-51.

Comments

This 8-item scale was originally developed and tested in Spanish for the Diabetes Self-Management study. For internet studies, we add radio buttons below each number. There is another way that we use to format these items, which takes up less space on a questionnaire, shown also in the PDF document. This scale is available in Spanish.

References

Unpublished.

This scale is free to use without permission.

**Self-Management Resource
Center** 711 Colorado
Avenue Palo Alto CA 94303
(650) 242-8040

smrc@selfmanagementresource.com

www.selfmanagementresource.com

Appendix Q

Announcement to Leadership

From: VanWageningen, Andrellie <A.VanWageningen@hhs.sccgov.org>

Sent: Thursday, June 3, 2021 10:06 AM

To: Salmon, Patricia <Patricia.Salmon@hhs.sccgov.org>

Cc: Magnampo, Romida <Romida.Magnampo@hhs.sccgov.org>; CamberosMedina, Laura <Laura.CamberosMedina@hhs.sccgov.org>; Teron, Michelle <michelle.teron@hhs.sccgov.org>

Subject: Diabetes Education Meeting Request

Hi Dr. Salmon,

I am so glad to hear that we are resuming the DM education meeting this month. Does it mean you will be back soon at VSC? Just want to give you a few updates:

- a. We are almost ready to enter data on the ASR Portal. I just need to go over it one more time. **Great work!**
- b. Michelle and Laura successfully completed their ADA DSME Coordinator training with me. I am confident that they will do a great job keeping VSC DSME Program running. **I agree. We have a great team!**
- c. I will be stepping down as the ADA QI Coordinator soon as I submit the ASR this month, and one of them will be the taking my spot.
- d. I am willing to assist them in the next year's DSME Renewal Process if you and Romida are okay with it. We have started discussing the process, and the renewal period starts in January 2022. **We will always welcome your support (and you'll forever be part of the DM team)**
- e. We worked on revising our materials and curriculum, kudos to Michelle's artistic talent on animation and Laura's bilingual ability. **Great work!**
- f. Laura and I completed the two sessions with Emory University's Diabetes Training Center to better understand their nationally recognized DSME program for Latinos, which will help Laura get the virtual/live DM classes that we want to get started soon. **Love this.** Let us know when you would like to resume the English and Spanish group classes. We can start slow and steady (e.g., virtual)? **I think we should start ASAP.**

Might have to start virtual depending on VMC policies on in-person group visits, although if classes are small, I would think we could do some in-person sessions.

For the upcoming meeting, do you think Laura and Michelle can have a few minutes to discuss the changes in the DSME survey tool, curriculum, and ADA DSME Accreditation status?

Absolutely! We hope you are well. We miss you and see you soon.

Thank you.

Andrellie

Appendix R

Course Evaluation (English)

1. Would you recommend this class to your family members or friends?

Yes

No

2. Was the instructor effective in teaching?

Yes

No

Additional Comments about the course:

