Title

Culturally Adapted Shared Medical Appointments in Primary Care: An Innovative Approach to Reduce Health Disparities among Low Income Latinos Living with Type 2 Diabetes

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Culturally Adapted Shared Medical Appointments in Primary Care: An Innovative Approach to Reduce Health Disparities among Low Income Latinos Living with Type 2 Diabetes

by

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DISSERTATION

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Dedication

I dedicate this dissertation to my daughters, Lena and Lucia. May you always follow your dreams and reach for the stars! I also want to dedicate this dissertation to my grandmother, Julita, who loved me unconditionally. To all my patients, who despite all the inequities in our system, continue to have hope and persevere in their search for a healthier life for themselves and their families. I want to acknowledge my family, Madeline, Lena and Lucia who have given me the daily support and love I needed to pursue my Doctorate. Thank you Lena, for editing my conclusion, and Lucia for helping with formatting the document. Also, to my mother who has always been my inspiration and role model. For believing in me and supporting me in all of my choices. To my father, who despite the distance has loved me unconditionally. Thank you for always accepting me as I am, and for your quiet and constant support. To my stepfather, for his support, and for sharing his best chocolate. I am grateful to the Department of Family Health Care Nursing, my colleagues and staff who have supported me throughout these years. Lastly, I want to thank my dissertation committee, Catherine Waters, Kit Chesla and Abbey Alkon. Kit and Abbey, thank you for believing in me, for letting me pursue unknown paths, for your mentorship and for your unconditional support.

Abstract

Diabetes presents a major public health problem worldwide and in the United States. Diabetes is among one of four non-communicable diseases being targeted by the World Health Organization. It is estimated that there are 422 million adults living with diabetes worldwide, that is 1 in 11 people. Likewise, 1 out of 11 people in the U.S. have diabetes, a total of 29 million people. The American Diabetes Association in the U.S. has created standards for the medical care and diabetes self management education and support (DSMES) for people with diabetes. Over the last 20 years DSMES has proven effective in improving physiological and psychosocial outcomes. Despite this, only half the people living with type 2 diabetes are currently at goal for their A1C and only 48% ever attend a program for DSMES. Shared Medical Appointments (SMA) have been proposed as one way of redesigning care to bridge this gap. Evidence from the last 15 years supports the implementation of SMA. This dissertation presents three manuscripts. The first is an integrative literature review on the effectiveness of SMA in treating type 2 diabetes. The second, describes the cultural adaptation process of ALDEA, (Latinos con Diabetes en Acción), a culturally adapted SMA program for Latinos with type w diabetes. The third manuscript describes the ALDEA SMA study. This is a six-month study of the effectiveness of ALDEA, a culturally adapted SMA clinic, for adult Latinos with type 2 diabetes, to improve hemoglobin A1C (A1C), low density lipoprotein (LDL) and blood pressure, compared to usual primary care (UPC). This quasi-experimental matched-controlled study included measures at baseline, 3 and 6 months. Results showed that after six months of treatment, SMA participants had achieved target A1C and had significantly greater reductions in mean A1C values compared to UPC . There were no statistically significant differences in the percentage of participants who achieved target LDL and blood pressure at 6 months between ALDEA and UPC. Results are clinically significant and provide initial evidence that ALDEA is an effective program that can potentially reduce health disparities in diabetes outcomes for adult Latinos.

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Introduction

Over the last few decades diabetes has reached epidemic proportions in the United States (U.S.). According to the Center for Disease Control (CDC) National Diabetes Statistics Report (2014), there are currently 29.1 million people or 9.3% of the U.S. population living with diabetes. Of those, 21 million have been diagnosed and 8.1 million are undiagnosed. Among adults the largest rate is among those 65 and older (25.9%), followed by those 45-64 (16.2%) [1]. Although diabetes affects all socioeconomic and ethnic groups, disparities in diabetes morbidity and mortality rates among racial and ethnic minorities persist. Non-Hispanic whites have the lowest incidence (7.6%), followed by Asians (9%), Hispanics (12.8%), Non-Hispanic blacks (13.2%) and American Indians/Alaskan Natives (15.9%)[1]. It is important to note that within-group differences are found among ethnic groups. In fact, differences within each ethnic category are as significant as between ethnic groups. Among Latino adults, the age-adjusted rate of diagnosed diabetes was 8.5% for Central and South Americans, 9.3% for Cubans, 13.9% for Mexican Americans, and 14.8% for Puerto Ricans. Among Asian American adults, the age-adjusted rate of diagnosed diabetes was 4.4% for Chinese, 11.3% for Filipinos, 13% for Asian Indians, and 8.8% for other Asians. Lastly, among American Indian and Alaskan Native adults, the age-adjusted rate of diagnosed diabetes varied by region with the lowest among Alaska Natives (6%) and highest among American Indians in southern Arizona (24%)[1]. The differences in rates within ethnic groups point to the importance of not being limited by social categories of race or ethnicity and to incorporate social determinants of health such as education and socio-economic status of populations in an analysis of this epidemic.

Diabetes complications are significant and include heart disease, stroke, chronic kidney disease, blindness, amputations of hands and feet, and severe gum disease[1]. While all people with diabetes are at risk, complications tend to be more common and more severe among those patients with poor control of their diabetes. Diabetes is the principal cause of kidney failure. It accounted for 44% of all new cases in 2011 and 60% of cases of non-traumatic lower extremity amputation in 2010 [1]. Furthermore, diabetes is a major cause of cardiovascular disease among U.S. adults. According to the CDC National Diabetes Statistics Report, between 2003-2006, after adjusting for population age differences, cardiovascular disease death rates were about 1.7 times higher among adults aged 18 or older with diagnosed diabetes than among those without the diagnosis. In 2010, after adjusting for population age differences, hospitalization rates for heart attack were 1.8 times higher, and for stroke 1.5 times higher among adults 20 and older with diagnosed diabetes [1].

In 2011, there were about 282,000 emergency room visits for adults 18 or older due to hypoglycemia and 175,000 for hyperglycemic crisis. In 2010, there were 2,361 deaths due hyperglycemic crisis. Diabetes is the seventh leading cause of death in the U.S. Additionally, between 2003-2006, after adjusting for population age differences, rates of death from all causes were about 1.5 times higher for people with diabetes [1].

Diabetes presents significant financial burden for diagnosed individuals , their families, communities, and the entire nation. Between 2007 and 2012, the total estimated annual cost increased by 41% to $245 billion, including $69 billion in reduced productivity due to disability, work loss and premature death [1]. Medical expenditures among persons with diabetes is two to three times that of persons without diabetes. Moreover, the largest component (43%) of total medical expenditures among people with diabetes is attributed to hospital inpatient care [1].

It is important to create a context for the alarming rates of pre-diabetes, obesity and diabetes among Latinos in the U.S. The socioeconomic position of an individual within an industrial society influences their health [2]. In fact, the socioeconomic position of an individual has graduated and continuous effects on health that are cumulative over a lifetime [2]. Findings from a recent study revealed that young racial/ethnic, foreign-born, and poor adults might be especially vulnerable to early onset and rapid progression of poor health as evidenced by marked disparities of high school completion among these groups. Thus, when designing health promotion and education programs it becomes imperative to have awareness of social determinants of health and the environmental barriers experienced by people with diabetes. Furthermore, a truly successful intervention must be accompanied by structural changes that will increase access to care and a healthy lifestyle.

Obesity significantly raises the risk for developing diabetes. Fat distribution and abdominal obesity are associated with altered glucose homeostasis and insulin resistance [8]. Subsequently, obesity and the resulting altered glucose homeostasis and abnormal insulin levels lead to increased risk for diabetes. With the disease, higher rates of poor glycemic control and less self-monitoring lead to increased risk for developing complications [5]. For Latinos, the rates of obesity are significantly higher than for their White counterparts, 42.5% vs. 34.5% [9]. Moreover, there is a socioeconomic gradient such that those with higher income and higher educational levels have lower rates of obesity for all ethnic groups [10]. Several factors contribute to this pattern of obesity rates, including poverty, food insecurity, food environment, neighborhood safety, lifestyle and poor nutrition [2, 10]. Latinos are more likely to have a sedentary lifestyle (62%) than non-Hispanic whites (56%) [11]. Lower levels of physical activity combined with increased calorie intake and fat consumption cause higher cholesterol levels,

which contribute to increased insulin resistance and insulin demands [5]. Further compounding the issue is that a disproportionate number of Latinos (29%) live in low income neighborhoods compared to whites (23%) [12]. These socioeconomically disadvantaged neighborhoods tend to have an abundance of fast food restaurants and convenience stores that are associated with higher rates of obesity and diabetes [12].

Several factors play important roles in the pathogenesis of type-2 diabetes including aging, genetics, lifestyle, and environmental risk factors [6]. The reason for the higher prevalence of diabetes and its complications among Latinos is multidimensional and thought to be related to genetic and environmental factors. Latinos in the US have a higher incidence of insulin resistance, obesity and metabolic syndrome. This is compounded by a lack of access to proper nutrition, safe recreational facilities, and increased psychosocial stress. Socioeconomic factors are inevitably intertwined with all of the mentioned risk factors [7].

Limited access to healthcare is also associated with increased risk for developing diabetes and its related complications [5, 13]. Language and communication are barriers for healthcare access, but one of the major limitations is lack of insurance coverage[13]. Latinos have the highest uninsured rates of any racial or ethnic group in the U.S. [14]. Uninsured persons are less likely to receive routine checkups, preventative services, and treatments, which elevate their risk to remain undiagnosed until severe illness and complications develop [14]. People with diabetes who have insurance coverage are more likely to have a source for health care, receive important exams and screenings, and receive and take medications for diabetes, all of which curtail diabetes associated complications [14]. A recent study reported that approximately 38% of Latinos who have diabetes reported not having health care coverage, over 40% did not know how many times per year they saw a doctor, and were less likely than other ethnic and racial

groups to self-monitor blood glucose [15]. Unfortunately, the high rate of uninsured among Latinos in the U.S. limits their access to medical care and preventative services, putting them at an unnecessarily increased risk for getting diabetes, going undiagnosed, and for developing associated complications.

To manage diabetes properly, individuals must address multiple lifestyle modifications, which make self-management a complex and difficult task. Studies have demonstrated that as many as 50 to 80% of patients with diabetes lack critical knowledge and skills necessary to manage their disease [20]. Difficulty adhering to prescribed medications and lifestyle recommendations is also a common problem [21, 22].

Adherence varies across domains of self-management, and is highest for medication administration and lowest for diet and exercise adherence [23, 24]. Only 36.3% of adults with Type 1 diabetes and 28.1% of adults with Type 2 diabetes meet the current guidelines of 150 minutes of moderate physical activity per week [20]. Similarly, only 23% of adults eat the recommended five portions of fruits and vegetables [25].

Multiple factors can contribute to adherence difficulties and or barriers to diabetes self-management care. For example, some patients lack the knowledge and skills related to maintaining appropriate glucose levels [26]. Likewise, patients may believe that following the recommended regime is unrealistic and arduous. Because blood glucose in patients with diabetes can sometimes fluctuate widely, despite good self-management, measuring regularly can negatively affect individuals' self-efficacy and may create distress [26]. Individuals with diabetes may feel isolated or develop conflict within their interpersonal relationships; some patients may demand very strict adherence and loved ones may provide little support or give little importance to necessary regimens [26, 27]. Moreover, maintaining

such a restricted lifestyle can be inconvenient, difficult, and discouraging, especially when patients may not see immediate rewards or reinforcements to continue following healthy behaviors. The lack of tangible benefits of behaviors aimed at preventing long-term complications might adversely influence patient motivation [26].

Patient education and self- management support is at the core of strategies used to help patients adhere to the complicated demands of diabetes care and are considered necessary to improve patient outcomes [3]. The ADA created the National Standards for Diabetes Self-Management Education (DSMES) and Diabetes Self-Management and Support (DSMS), which is designed to facilitate quality and evidenced-based education. The objectives of the DSME are "to support informed decision-making, self-management behaviors, problem-solving and active collaboration with the healthcare team and to improve clinical outcomes, health status and quality of life" (ADA, 2017, p. S89). These standards became the guiding principles for self- management education programs, and inform providers about how programs should be delivered, assessed, and incorporated within patient care. The guidelines are rigorous and following them requires the use of multiple financial, professional, and time resources.

Several review studies have assessed the effectiveness of DSMES educational programs on the general population with diabetes and have identified key characteristics for improving glycemic control [28-31]. Effective self-management interventions include a combination of aspects such as patient education and self-management training, behavior modification, and psychosocial support. Furthermore, face-to-face delivery and higher contact time appear to be of importance in affecting physiological markers such as hemoglobin HbA1C. [30] [31].

Researchers have developed multiple interventions with the purpose of teaching,

motivating, encouraging, and increasing self-management behaviors in patients with diabetes [32]. These interventions range from individual and group education [31] to programs that target specific behaviors or needs of individuals with diabetes [30]. The goal of most interventions is to empower patients to be in charge of their health through knowledge, skill building, problem solving, and coping skills for day-to-day issues related to their disease [3]. While many programs are initially effective at increasing patient knowledge, self-management behaviors, and glycemic control, improvement is not typically maintained long-term, or patients require frequent repetition and time intensive case management to experience lasting effects [30]. Additionally, knowledge and education per se do not always correlate with glycemic control and a healthy HbA1C [27].

Diabetes complications can be prevented with effective medical management and tight glucose control [3]. To eliminate disparities and suffering from diabetes experienced by Latinos, and the economic costs associated with complications, access to culturally appropriate education and effective disease management must be improved. Increasing effective healthcare and improving self-management are important to minimizing the burden of diabetes on this vulnerable population [31].

More than two decades of studies have demonstrated the effectiveness of culturally-tailored DSME in improving health outcomes in Latinos with type-2 diabetes [28]. Latinos are attracted to DSME programs because they incorporate group learning and sharing, social networking and building disease management skills through physical activities, diet control, blood glucose monitoring, medications use, and awareness of potential complications [28]. Despite this, racial and ethnic minorities are less likely to engage in DSME behaviors [20].

A recent meta-analysis of diabetes self-management educational programs for racial/ethnic minorities concluded that DSME that are culturally tailored are effective in reducing fasting blood glucose, HbA1C and blood pressure [31]. Authors reported the meta-analysis was conducted to estimate the pooled difference in HbA1C between the intervention and control group immediately after the intervention was completed, observing a significant reduction in the overall HbA1C of -0.31% (95% CI -0.76% to -0.17%) among group participants. Of the 20 studies included in the meta-analysis, only 3 measured HbA1C at 12 months post intervention. A meta-analysis of these three studies observed a reduction in pooled HbA1C of -0.47%, although no significant differences were observed ($p = 0.13$) between the treatment and control condition, This finding corroborates with a previous meta-analysis with the general population [30] that educational interventions while effective initially, lose potency over time.

Ricci-Cabello and colleagues conducted a second meta-analysis to identify characteristics of interventions associated with increased short -term reductions in HbA1C. Interventions delivered face –to- face, included a peer educator and those employing cognitive reframing techniques were associated with better outcomes. Interestingly, no statistically significant differences were found based on number or duration of group sessions, or the total number of hours or its intensity [31]. It is important to point out that the 0.31% reduction in HbA1C observed in this meta-analysis, while modest, it is of clinical significance as evidenced by research that suggests every percentage point decrease in HbA1C over years is associated with a risk reduction of 21% for deaths related to diabetes, 14% for myocardial infarctions, and 37% for microvascular complications [33].

The finding that interventions based in cognitive reframing techniques produce better outcomes corroborates with a previous meta-analysis of educational interventions in the general

population [30]. Furthermore, it supports previous research that knowledge is a necessary, but not sufficient factor required for behavior change [34, 35].

Despite the proven efficacy of DSME and the fact that it is at the cornerstone of standard medical care for diabetes, only half of adults with diabetes reported ever receiving formal diabetes education or attending self-management classes [4]. Furthermore, providers are often not aware of education options or content of available classes. Patients who do attend a class often receive basic information and are then left to manage their disease for the rest of their life on their own [32]. Others receive the majority of their education from their primary care providers. However, most individual visits with a provider are problem-focused and do not allow enough time for education or cognitive restructuring interventions [18].

With the current 1:1 patient-provider approach in primary care, fewer Latinos diagnosed with diabetes receive standard care for their diabetes, such as immunizations, foot examinations, ophthalmology screenings, and most importantly, diabetes education, compared to their non-Hispanic white counterparts [5]. In response to this gap in standard diabetes care, the American Diabetes Association (ADA) (2017) called for changes in delivery of care by incorporating the Chronic Care Model to improve diabetes management and outcomes [3].

Shared medical appointments (SMA) are an increasingly popular method aimed at improving access to DSME and primary care services in order to decrease diabetes and related complications [30, 36]. SMAs are a promising alternative to individual office visits that integrate DSME and peer support within the primary care visit. They also nurture collaborative relationships between providers and patients while group activities refine disease management skills and enhance knowledge. They offer an innovative option to meet the various medical and educational needs of Latino patients living with diabetes [36].

The three manuscripts presented for this dissertation are: (1) Shared Medical Appointments for People with Type 2 Diabetes: An Integrative Literature Review; (2) Cultural Adaptation of ALDEA (Latinos con Diabetes en Acción): A Description of the Adaptation Process of a Shared Medical Appointment Model for Latinos with Type 2 Diabetes and, (3) Shared Medical Appointments: An Innovative Model to Reduce Health Disparities Among Latinos Living with Type-2 Diabetes ALDEA: Latinos con Diabetes en Acción. The first paper is an integrative literature review on SMA effectiveness for type 2 diabetes. The second paper describes the process of cultural adaptation of an SMA model, namely ALDEA (Latinos con Diabetes en Acción). Lastly, the third paper presents data from the quasi-experimental study of ALDEA to evaluate its impact on diabetes outcomes.

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Shared Medical Appointments for People with Type 2 Diabetes: An Integrative Literature Review

Introduction

Diabetes has reached epidemic proportions in the United States (U.S.). There are currently 29.1 million people or 9.3% of the U.S. population living with diabetes. Type 2 diabetes accounts for 95% of the cases nationwide. Among adults, the highest rate of diabetes is among those 65 and older (25.9%), followed by those 45-64 (16.2%) [1]. Moreover, although diabetes affects all socioeconomic and ethnic groups, disparities in diabetes morbidity and mortality rates among racial and ethnic minorities continue to persist. Non-Hispanic whites have the lowest incidence (7.6%), followed by Asians (9%), Hispanics (12.8%), Non-Hispanic blacks (13.2%) and American Indians/Alaskan Natives (15.9%).

Diabetes complications are significant and include heart disease, stroke, chronic kidney disease, blindness, amputations of extremities, and severe gum disease [2]. While all people with diabetes are at risk of these complications, they tend to be more common and more severe among persons with poor diabetes control [1]. In 2011, there were about 282,000 emergency room visits for adults 18 years of age or older due to hypoglycemia and 175,000 for hyperglycemic crises. In 2010, there were 2,361 deaths due to hyperglycemic crisis. Diabetes is the seventh leading cause of death in the U.S. Additionally, between 2003-2006, after adjusting for population age differences, rates of death from all causes were about 1.5 times higher for people with diabetes [2].

Although progress has been made over the last couple of decades, only 53% of people with diabetes achieve goals for HbA1C, 72% for blood pressure, 56% for low density lipoprotein, and only 19% meet all three goals [3]. Moreover, although Diabetes Education and

Self Management Support (DSMES) is a core component of diabetes medical care, only half of patients ever obtain DSMES [3]. The current health care system is failing to provide comprehensive care to a large number of people with diabetes, and the American Diabetes Association has called for a system redesign using the Chronic Care Model [4]. Shared Medical Appointments (SMA) have been proposed as one viable option to address this gap in diabetes care [5].

Shared medical appointments (SMA) are becoming a common model of care delivery in primary care settings [6, 7]. In this model of care medical visits are offered in a group setting and incorporate group process, problem solving, behavior change interventions, diabetes education, and medical care [8]. Shared medical appointments vary in their format, the composition of team members and the length and longevity of each group [9]. The commonalities among SMAs are that they incorporate medical evaluation, medication adjustment and coordination and delivery of preventive services in the context of a multidisciplinary team [9]. Additionally, SMAs foster discussion among participants and health care providers and participants experience support from other people who experience similar health concerns [10].

The purpose of this paper is to provide a summative literature review of the effectiveness of shared medical appointments to improve diabetes outcomes for people with type 2 diabetes. The review is organized by outcome measures and it attempts to provide a summary of the evidence for each outcome, followed by a synthesis and recommendations for future research.

Shared Medical Appointments: Literature Review

Data sources and search strategy

A search was conducted in October 2016 on multiple databases (MEDLINE® via PubMed®, Cochrane Register of Controlled trials, CINAHL (EBSCO), and PsycINFO using terms for prescribing practitioners and shared medical appointments, including terms for group education, group program, group session(s). Additional articles were obtained from reference lists of pertinent studies. Articles included are in English-language, randomized controlled trials (RCT) of SMA visits led by prescribing facilitators for patients with diabetes mellitus type 2 (T2DM). Studies were excluded if they focused exclusively on groups providing support, exercise guidance or did not include individual-level treatment plans or prescription changes, elements essential to SMAs. Furthermore, studies published before 1998 were excluded because the overall approach to adult diabetes care was qualitatively different after the publication of the UK Prospective Diabetes Study, thereby rendering older studies less applicable [11]. The search produced a total of 9 RCTs.

Review of Share Medical Appointment's Literature

Over the last 15 years research has emerged on the effectiveness of SMAs as a way to deliver medical care and diabetes education [9]. The review of 11 RCTs synthesizes the evidence and sheds light on this body of research. All but one of the RCTs, took place in the U.S. All of the studies were conducted in primary care settings. A majority of the studies were based in the Department of Veteran Affairs (6 studies); two studies were conducted in University Centers, two in Health Maintenance Organizations, and one in a community setting.

Discussion of the literature review is organized in the following sections: structural components of groups, medical management, biophysical outcomes, psychosocial outcomes, economic outcomes and literature synthesis. See Tables 1 and 2 for a summary of the studies.

Structural Components of Groups

Shared medical appointments were conducted by multidisciplinary teams of one to seven clinicians. A physician led most of the groups and a registered nurse was part of the team in all of the groups. A mental health professional and a pharmacist were part of the teams in approximately 50% of the studies. Nurse practitioners were not part of the team in any of the studies. All studies used a closed group panel of patients. Group size was 6 to 10 for most studies, with group size ranging between 10 and 20 in four studies and group size as large as 25 members in one study. The planned visit frequency ranged from every 3 weeks to every 3 months. Shared medical appointment visits were a median of 2 hours and ranged from 1 to 2 hours. All of the SMAs in these studies offered individual consultation with a physician or clinical pharmacist for individual medication management. About half the studies invited participation by family members or friends. Lastly, seven of the 11 studies included behavioral approaches to diabetes management education and four were purely didactic.

Sample Demographics.

Medical Management: Patient Medication Adherence and Medication Titration

Medication titration was reported inconsistently in the studies. One study reported a statistically significant higher number of medication starts or dose titrations for oral hypoglycemic medications among SMA's participants versus usual care participants [12]. In another study, a higher number of insulin starts and insulin doses were reported for SMA participants as compared to usual care participants [6]. Taveira and colleagues (2011) also reported more antihypertensive medication starts or dose titrations overall in the SMA

intervention group compared to the usual care group. In addition, the researchers found a statistically significant greater use of dose titrations for selected antihypertensive medications among SMA participants compared to the usual care group [12]. Only one study monitored medication adherence and found no differences between SMA and usual care participants [13].

Biophysical Outcomes

HbA1C

Seven of the studies included in this review reported SMAs to be more effective than usual primary care in reducing HbA1C [6, 10, 12, 14-17], while four did not [8, 13, 18, 19]. An interesting pattern emerged when the components of the SMA interventions were examined. While no two SMA approaches were the same, the inclusion of behavioral approaches to diabetes management was a commonality among studies and these studies found a significant effect of the SMAs on reductions in HbA1C. The four studies that found a non-significant effect had interventions that included a medical evaluation, peer interaction, support and education, but did not focus on behavioral approaches for diabetes management [8, 13, 19, 20]. This pattern, were SMA that prove to be effective include behavioral approaches, was corroborated by Naik and colleagues in the only RCT do date evaluating the comparative effectiveness of two diabetes group interventions. One of the interventions, EPIC, included behavioral approaches and the second included a traditional didactic approach for diabetes management. Compared to usual care participants in the EPIC intervention had significantly greater improvements in HbA1C levels immediately following the intervention; HbA1C levels decreased significantly by 0.82% in the intervention group versus .04% in the usual care group. These differences between groups persisted at the 1-year follow-up (0.59% [1.4%],p=.05). Furthermore, a repeated-measures analysis using all study

time points found a significant time-by-treatment interaction effect on reducing HbA1C levels favoring the EPIC intervention over usual care ($F(2,85)=3.55$, $p=.03$). In other words, the EPIC intervention had a significantly larger HbA1C change compared to usual care.

Cholesterol

Only three studies included total cholesterol as an outcome and they did not find a statistically significant decrease in cholesterol [10, 19, 20]. Likewise, four studies reported non – significant decreases in low density lipoprotein (LDL) [6, 12, 15, 21]. Edelman and colleagues also reported a non-significant effect of SMAs on changes in patient's cholesterol (Δ = -6.6 mg/dl (95 % CI: 2.8, -16.1) [7].

Blood Pressure

Five of the eleven studies included in this review reported blood pressure as an outcome [6, 7, 12, 15, 16]. In all five studies, statistically significant improvements in achieving blood pressure control post intervention were found between participants in the SMA and control groups. Four of the five studies took place within the VA system with primarily White and male participants. This unfortunately limits the generalizability of the findings. The study by Schillinger et al. (2009) was conducted in an urban community setting with a multi-ethnic sample, thus broadening the generalizability of the significant effect of SMAs in achieving blood pressure control.

Psychosocial Outcomes

Six of the eleven RCT in this review included psychosocial outcomes.

Health Related Quality of Life Outcomes

In three studies, health related quality of life (HRQOL) outcomes were reported. In contrast to one of the studies [11], in the other two studies, statistically significant differences in HRQOL were found between SMA and control participants [14, 19]. The lack of statistical significance in HRQOL between SMA and usual care groups in Cohen's study might be due to the short follow-up time frame in the study [11]. Again, generalizability of these findings is limited. Trento's study took place in Italy and Wagner's sample, 30% of whom were non-Caucasian, were largely highly educated (90% of the sample had >12 years of education).

Self-Efficacy

Only three studies included self-efficacy as an outcome ([14, 16, 17]. Naik and colleagues (2011) used the Diabetes Self Efficacy scale, a valid and reliable scale [22]. In a comparative effectiveness design of SMA groups with EPIC or education components self-efficacy scores improved significantly from baseline to 3 months only in the EPIC intervention group (mean(SD) =0.84 (1.56), *P*=.02). Diabetes self-efficacy scores returned to baseline levels at the 1-year follow-up for both SMA groups with modest, non-significant between group differences (mean (SD)=0.62 (1.94), *P*=.17). A secondary repeated measure analysis was computed to evaluate the mediation effect of diabetes self-efficacy on time by treatment interaction and longitudinal differences in HbA1C. The results showed significant effects for self-efficacy ($F(1,85) =10.39$, $p=.002$). Time by treatment interaction on longitudinal HbA1C values became non-significant once self-efficacy was adjusted ($F(2,85)=2.93$, $p=.059$). Thus, the authors concluded that self-efficacy appears to mediate the effect of the SMA and HbA1C.

Lastly, Schillinger and colleagues (2009) found a significant improvement in self-efficacy in SMA group participants compared to usual care group participants (B=0.38,p=0.008).

Self-efficacy appears to be an important variable that has been mostly excluded in the SMA literature. However, it is encouraging that all three RCTs that assessed self-efficacy, found significant results with three very different patient populations, strengthening the generalizability of the findings. The three samples were highly educated mostly Caucasian sample in an HMO [14], mostly male veterans [15] and a multicultural community-based sample ([16]. Finally, Cohen's finding that self-efficacy is a mediator in the effectiveness of SMA to reduce HbA1C is of special interest as it points to an important skill that should be targeted in future interventions.

Diabetes Knowledge

Diabetes knowledge is another outcome that was included in only one study [10, 17]. The study reported knowledge of diabetes improved significantly among participants in the SMA (p<. 001), but not in the control group (p<.05) [10].

Self-Care or Self-Management Behavior

Three studies included self-care or self-management as an outcome variable [14-16]. Cohen et al. reported the number of days of the week that patients followed foot care recommendations was significantly higher for SMA participants (1.46 days, 95% CI: 0.75, 2.18) than for usual care participants (0.47 days, 95% CI: −0.16, 1.09). Additionally, SMA and usual care participants had similar improvements in compliance with diet and exercise ADA recommendations.

In a study of participants who attended an SMA program at an HMO were significantly more likely to see a nutritionist ($p<0.001$) and have a home blood glucose monitoring (<0.0001) compared to the usual care participants [14]. Lastly, Schillinger and colleagues (2009) reported SMA participants showed significant increases in the following self-management domains, self-monitoring of blood glucose and an increased for diet and exercise behaviors after intervention, compared to usual care participants.[16]

Economic Outcomes

Hospital Admissions and Emergency Room Visits

The effect of SMA on hospital admissions and emergency department visits was reported in five studies [6, 7, 14, 19, 21]. Three of the studies found that hospital admissions rates were significantly lower in SMA participants than usual care participants, 6-18 months after the intervention [14]. Hospitalizations were 80% more frequent among participants in usual care participants compared to SMA participants ($P = 0.04$) (REF). Although not statistically significant, Wagner and colleagues found that hospital admissions were lower in SMA participants (17%) compared to usual care participants (21%) two years after baseline. Two of the studies found significantly less emergency department visits in the SMA group versus the control group within one year of the study [7, 19].

Synthesis of Literature and Recommendations for Future Research

The most robust evidence on the effectiveness of SMA is on the impact on biophysical outcomes. There is sufficient evidence of the effectiveness of SMAs on lowering HbA1C and blood pressure which supports the implementation of SMA among people with type 2 diabetes

[7, 9]. However, there is insufficient evidence that SMAs can have an significant effect on cholesterol levels [7]. The impact of SMA on HbA1C and blood pressure is not only statistically significant, but also, more importantly, it is clinically significant. Edelman and colleagues' meta-analysis revealed that SMAs improved HbA1C by 0.6 percentage points, findings similar to another meta-analysis [9]. While a change of 0.6% may seem modest, based on the UKPDS findings [11], a decrease of 0.6% HbA1C translates to a decrease of approximately 10.5% deaths related to diabetes, 7% myocardial infarctions, and 19% micro-vascular complications. Edelman et al. also found a clinical significant change of 5 mm/Hg in systolic blood pressure among SMA participants. To provide context, a classic anti-hypertension study found that after adding a first line medication for hypertension treatment the expected improvement after one year of treatment was of approximately 6.6 mm/Hg [23]. Edelman points out that SMA patients achieved 75% of the level of improvement seen with a first line medication for hypertension[7].

The literature is not as robust, nor is it clear that SMAs are effective with regards to psychosocial outcomes. Except for HRQOL, non-biophysical outcomes have not been included in meta-analyses due to the lack of reporting and heterogeneity of measures [13]. Few studies included psychosocial outcomes and measurement tools varied across studies making it difficult to draw clear conclusions. Nonetheless, the current literature suggests promising effectiveness of SMA in improving diabetes self–efficacy [14, 16, 17]. Of particular interest is that self-efficacy was found to mediate the relationship between SMA and HbA1C outcomes [15] and HRQOL was the only psychosocial variable found to improve the lives of people with diabetes who participated in SMAs

At this point in time it is difficult to draw conclusions about the effectiveness of SMA on health care utilization and cost. Only four of the studies included in this review found a

reduction in hospitalization rates and only one was statistically significant [14]. Although Wagner et al. found a statistically non-significant 17% reduction in hospital admissions among SMA participants compared to usual care participants. While this finding was not statistically significant, it is of significance when one considers a 17% reduction in hospital admissions translates into significant savings for the health care system as a whole. This gap in the literature points to an important area for future research.

Despite 10 -15 years of research on the effectiveness of SMA on diabetes outcomes, the literature continues to have gaps. A major gap is the difficulty of contextualizing what elements of an SMA intervention are the strongest independent predictors of the outcome. Perhaps the different elements work synergistically. Today, there is a broad agreement on what constitutes a SMA, i.e. a group visit that includes a medical visit and peer interaction, but there is no consensus on the optimal size or composition of the team members, the number of sessions, or the duration of the program. More importantly, there is little consensus on how to conduct the groups. Some SMAs are purely didactic, while others incorporate cognitive behavioral approaches. In analyzing the evidence, it appears that SMAs that include behavioral approaches, in conjunction with education, had significantly better HbA1C outcomes; which was corroborated by Naik and colleagues, who found that SMAs that included behavioral approaches to diabetes management were more effective in reducing HbA1C than SMAs that were only didactic.

The effect of SMA on medication management was also not consistently reported in the literature. While two studies reported a significant difference in medication titration and insulin starts among participants in SMA [6, 12], no studies to date have explored whether intensity in medication management is responsible for improvements in physiological outcomes. Perhaps the

positive outcomes of SMAs are attributable to an interactive effect of behavioral approaches and more intensive medication management. Thus, future research is needed to identify what aspects of an SMA are responsible for the change in outcomes. Furthermore, future research must explore the role of each aspect of the intervention and how it affects outcomes. In other words, do SMA increase self-efficacy? And does an increase in self-efficacy mediate the effect of SMA and lower HbA1C? Additionally, does an increase in medication intensity[1] moderate the effect of SMA and lower HbA1C?

Another major gap in the literature is the lack of research among the populations with the highest rates of type-2 diabetes, Native Americans, African Americans and Latinos. The majority of the studies were among Caucasian males due to primarily being conducted in the Veteran Affairs healthcare system. Racial and ethnic minorities were included in small numbers in the samples, and when included, they were highly educated and had access to care. When Latinos were included in study samples, only those who spoke English were included. The exception was the Schillinger et al. study (2009) which was the first RCT that included a multicultural and multilingual sample. Thus, the current literature lacks external validity to the broader population.

Future research on the effectiveness of SMA as a model of care should attempt to close the gaps identified in the literature such as limited sample compostition and lack of standardized patient centered outcomes. In particular, comparative effectiveness studies are necessary to identify which components or types of an SMA are responsible for positive outcomes. Researchers should attempt to use standardized instruments across studies that will allow for meta-analysis, and include not only biophysical and psychosocial measures, but also patient-

[1] Medication Intensity is defined as higher titration rates and/or medication initiation rates.

centered and staff- centered outcomes. Finally, SMA is a major shift in the clinic organization and service delivery, and thus more data are needed on cost effectiveness before policy recommendations can be made.

In summary, SMA is a promising model of care for people with type 2 diabetes. Given the disproportionate rates of type 2 diabetes among Latinos in the U.S., it is imperative that research with this vulnerable population is developed. To date, there has been no RCTs to evaluate the effectiveness of culturally-specific SMAs with Latinos. There is enough evidence that diabetes self- management education programs are effective in improving outcomes for Latinos [22]. This presents us with a challenge and opportunity to contribute to the field by translating culturally specific self -management education and behavioral interventions into SMA for the Latino population in the U.S.

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Table 1

Study	Location • Country • Setting • Total N	Intervention • Type • Group Duration • Frequency • Study duration • Total #GMV	Design • Design • Timeline of Measures • HbA1C inclusion criteria	Participants • Average Age • HbA1C (Mean Baseline) • Ethnicity • Sex • Average Literacy • Exclusion Criteria	Outcome Measure	Results
Clancy et al., 2003	US Primary Care University Affiliated Clinic 120	• Didactic • 2-h • Monthly • 6 mo • 6	• RCT • Baseline, 36 mo	• 54 • HbA1C 10.4 • C • 75% F • 7th grade • NES	• TPS* • PCI* • Hospital Admission • HbA1C, • Lipids	SS*: [2]TPS (3,6,9) PCI (14,23,33) Hospital Admin NSS*: HbA1C Lipids.
Clancy et al., 2007	US Primary Care	• Didactic • 2-h • Monthly	• RCT: • Baseline, 6,12 mo	• 56 • HbA1C 9.1 • 82% AA, 33%C	• PCI • ER • Ca Scr*	SS: PCI

[2] TPS-Trust in Physician Scale; PCI-Process of Care Indicators (ADA); NES-Non-English Speakers; ER-Emergency room visits; HA-Hospital Admissions; CaSCR-cancer screens; SS-statistically significant; NSS-non-statistical significant; DSCB-Diabetes Self-care behavior;

	University Affiliated Clinic 186	• 12 mo • 12	• HbA1C> 8%	• 72% F • 6th grade • NES	• HA • HbA1C, • Lipids	Ca Scr NSS: HbA1C Lipids BP
Cohen et al., 2011	US Primary Care VA Health System 99	➢ Didactic and Behavioral • 2-h • WeeklyX1 mo; montly X 5mo. • 6mo • 9	• RCT: • Baseline, 6 mo • HbA1C> 7%	• 70 • HbA1C 7.8 • 42%C,54% AA • 100%male	• SCB • PCP # visits • HbA1C, • Lipids • BP	SS: HbA1C BP SCB NSS: QOL
Edelman et al., 2010	US Primary Care	• Didactic • 90–120min	• RCT • Baseline, 6,12 mo	• 62 • HbA1C 9.2 • AA 59%; C	• MA[3] • Hospital Admin	SS: SBP. NSS:

[3] MA-Medication Adherance; BP-Blood Pressure; EPIC-Behavioral Intervention; DSE-Diabetes Self-efficacy; DK-Diabetes Knowldege; SCB-Self-Care Behavior; SE-Self-Efficacy;ATS-Automated telephone Support; SS-Statistical Significant ;NSS-Non-statistical significant

	VA Health system 239	• 2mo • 12 mo	• HbA1C> 7.5%	41% • Male 96%	• ER • , HbA1C, • BP	HbA1C MA Hospital Admin ER
Naik et al., 2011	Us Primary Care VA Health System 87	• Didacticvrs. Epic * • 90-min • 3wk • 3 mo	• RCT • Baseline, 3m, 12 mo • HbA1C >7.5	• 64 • HbA1C 8.8% • AA 31%, C 69% • !00% Male	• DSE • DK • HbA1C	<u>SS:</u> HbA1C DSE DK
Sadur et al., 1999	US Primary Care HMO 185	• Didacti,+ case management,+ Behaviorist. • 120 min • Monthly • 6 mo	• RCT • Baseline, 6mo • HbA1C >8.5%	• 56 • HbA1C 9.7% • Multiethnic (75%C,15% L, 5%AA,7%A). • 42% women • >80% >HS Ed • NES excluded	• SCB • SE • HbA1C	<u>SS:</u> HbA1C SE SCB

Schillinger et al., 2009	US Primary Care Community Based County Clinic 212RCT:	• 1 arm Behavioral : 2 arm ATS • 90 min • Monthly • 9mo	• RCT:3 arm:GMV,ATS,Usual care • Baseline, 6m,12 mo • HbA1C >8%	• 56 • HbA1C 9.5% • Multiethnic/lingual sample • >50% limited Health Literacy	• PACIC • IPC[4] • DSE • SCB • BP • HbA1C	SS: PACIC SE SCB BP NSS: HbA1C
Taveira et al., 2010	US Primary Care VA Health System 118	• Didactic + Behavioral • 120 min • Weekly • 4m	• RCT • Baseline, 3m • HbA1C >7%	• 64 • HbA1C 8% • Caucasian 91% • 95% male	• HbA1C, • BP • Lipids	SS: HbA1C BP NSS: Lipids
Taveira et al., 2011	US Primary Care VA Health	• Didactic and Behavioral • 90-min	• RCT • Baseline, 6mo • HbA1C	• 60.8 • HbA1C 8.4% • Caucasian 99% • 98% Male	• CESD • PCI • BP • Lipids	SS: HbA1C

[4] PACIC-Patient Assessment of Chronic Illness Care; IPC-Interpersonal Process of Care; DSE-Diabetes Self Efficacy; PCI-Process of Care Indicator; CESD-Depression scale;DQOL-Diabetes Quality of Life; DK-Diabetes knowledge; SCB- Self Care Behavior;

	System 88	• WeeklyX 4 wk, then monthlyX 5 mo • 6 mo	>6.5%		• HbA1C	BP <u>NSS:</u> PCI Lipids
Trento et al., 2001	Italy Primary Care HMO 112	➢ Didactic+ Behavioral. ➢ Not reported ➢ 3mo ➢ 4yrs	➢ RCT ➢ Baseline, 6m,12,24 m,4yrs ➢ HbA1C NR	➢ 61 ➢ HbA1C 7.4% ➢ NR[5] ➢ Male 54%	➢ DQOL ➢ DK ➢ SCB ➢ Lipids ➢ HbA1C	<u>SS:</u> HbA1C QOL DK <u>NS:</u> Lipids
Wagner et al., 2001	US Primary Care HMO 707	➢ Didactiic ➢ Half-day sessions ➢ 3 mo and 6 mo) ➢ 2 yrs	➢ RCT ➢ Baseline, 3mo, 6mo	➢ 60 ➢ HbA1C 7.5% ➢ Caucasian 73% ➢ Male 53%	➢ QOL (SF 36subs) ➢ Hospital Admission ➢ ER	<u>SS:</u> QOL ER <u>NSS:</u>

[5] NR-Not rated;

					➢ Lipids ➢ HbA1C	Hospital Admission HbA1C

Note: ADA = American Diabetes Association, BMI = body mass index, BP = blood pressure, EQ-VAS = EuroQol 5-d measure of health outcome, HDL = high-density lipoprotein, LDL = Low-density lipoprotein, NS = not significant, SF-36 = Medical Outcomes Study 36-item Short Form.

Cultural Adaptation of ALDEA (Latinos con Diabetes en Acción): A Description of the Adaptation Process of a Shared Medical Appointment Model for Latinos with Type 2 Diabetes

Introduction

Type 2 diabetes constitutes an epidemic in the United States (U.S.). Moreover, disparities in diabetes morbidity and mortality rates among racial and ethnic minorities persist [1]. Latinos constitute the fastest growing ethnic group in the US. It is estimated that by 2050, the Latino population will double, even in the absence of immigration[2]. The National Healthcare Disparities Report of 2013 documented continued lack of improvement in diabetes quality of care indicators among Latinos [3]. The landmark Hispanic Community Health Study/Study of Latinos (2014) (HCHS/SOL) sheds particular light on the issue of heterogeneity of Latinos in the U.S. It reported an overall prevalence of diabetes among all Latino groups of roughly 17% for both men and women, compared to 10% for non-Hispanic whites. However, the diabetes prevalence rates vary among Latino subgroups with lower rates in South Americans (10%) and Cubans (13%) and higher rates among Central Americans, Dominicans, Puerto Ricans and Mexicans (18%) [4]. The HCHS/SOL found that 48% of Latinos with diabetes were uninsured and 58.7% were unaware of having diabetes based on discordance between self-report and laboratory results. Furthermore, only 48% of Latinos with diabetes demonstrated adequate glycemic control (HbA1C<7%, 53 mmol/mol) [4].

Structural barriers to health care and high costs of treatment can contribute to poor diabetes outcomes for Latinos and other disadvantaged racial/ethnic minority patients[5]. Lack of access, financial and language barriers, poor health literacy and numeracy, distrust of and perceived discrimination by health care providers are key factors influencing health care in this population [5]. Thus, when designing health promotion and education programs it is important to

consider social determinants of health, such as education and income, and the structural barriers, such as healthcare access and transportation, experienced by people with diabetes.

Diabetes self-management education and support (DSMES) is a critical component of standard medical care for people with diabetes, yet only half of all those diagnosed with diabetes report ever receiving DSMES [6]. With the current one-to-one patient-provider approach in primary care, fewer Latinos diagnosed with diabetes receive standard diabetes care, such as immunizations, foot examinations, ophthalmology screenings, and most importantly, diabetes education, compared to their non-Hispanic white counterparts [3].

Shared medical appointments (SMA) are an increasingly popular method aimed at improving access to DSMES and primary care services in order to decrease diabetes related complications[7]. SMAs are a promising alternative to individual office visits because they can integrate DSMES and peer support within the primary care visit. They also nurture collaborative relationships between providers and patients while group activities refine disease management skills and enhance knowledge [7]. Evidence of SMA effectiveness is robust regarding biophysical outcomes (e.g., HbA1C). Cumulative evidence on the effectiveness of SMA on HbA1C and blood pressure supports the implementation of SMA among people with type 2 diabetes [7-11].

The purpose of this paper is to describe the cultural adaptation process of a shared medical appointment program for low-income monolingual Spanish speaking Latinos in a community clinic setting, and to articulate the lessons learned at each phase.

Cultural Adaptation of Shared Medical Appointments for Type 2 Diabetes

Over the last decade, several models have been proposed to guide cultural adaptation of evidence-based interventions (EBI) in public health [12-14]. Castro (2010) points out that although these models were developed independently, they demonstrate considerable consensus in their processes[15]. A useful early stage model proposed by Barrera and Castro[15] delineates a sequence of five intervention adaptation stages consisting of (1) information gathering, (2) preliminary adaptation design, (3) preliminary adaptation tests, (4) adaptation refinement and adaptation trial[12]. This paper will use Castro's (2010) adaptation framework to describe the cultural adaptation process developed by the ALDEA SMA program for first generation Latinos living with type 2 diabetes, treated in a community clinic setting. ALDEA is a Federally Qualified Health Center located in the California Central Coast area. It provides full scope primary care to families regardless of their ability to pay. Currently, there is no health education department to provide diabetes education on site. There are no nutritionists, nor diabetes educators on staff. At the time this program was started there was only one diabetes education referral option for Spanish speaking patients and it is 20 minutes away by car. Thus, the creation of a program to bridge this gap in care was of utmost importance.

Stage 1: Information Gathering (Literature Review)

Stage 1 involves identifying cultural issues that are significant and important to consider in designing the intervention. Cultural adaptations are warranted when a subcultural group exhibits differences in the risk or resilience factors related to a health outcomes [16]. The term, Latino[6] or Hispanic, refers to persons of Cuban, Mexican, Puerto Rican, Central and South American origin, regardless of race. Latinos are a diverse group of people, wherein the intersection of ethnicity, race, class, education, immigration history and acculturation contribute

[6] In this paper the term Latino will be used instead of Hispanic.

to its complexity. The majority of Latinos residing in the geographical area where this intervention took place are from Mexico and El Salvador, are low income and underinsured (P.Hernandez, personal communication, November 3,2015). Thus, the cultural adaptation for this intervention took into account structural barriers, social determinants and cultural aspects of this particular demographic: low income, underinsured to uninsured Latinos of Mexican and Salvadorian origin.

Structural Barriers

Among the risk factors that have been identified as possible barriers to diabetes self-management among low income Latinos are lack of health insurance, low socio-economic status, low health literacy, food insecurity, low diabetes knowledge, language barriers and low acculturation levels, [17].

According to the National Healthcare Quality and Disparities Report (2015), Latinos are overrepresented among the poor in the United States. While they constitute only 17% of the population, they represent 37% of the American poor. Moreover, they are the group with the highest uninsured rate, with 25% of the population lacking any form of health insurance [18]. Financial barriers to medication use is reported in significantly greater numbers among low income Latinos compared to their White conterparts [19] .

Low health literacy and illiteracy are prevalent among Latino immigrant patients, particularly for those from Central America and Mexico [20] . A recent study found that more than half of Latino patients with diabetes (52%) had low health literacy[21] an important figure given that a significant correlation was found between low health literacy and glycemic control in this sample.

Food insecurity, defined as not having "access at all times to enough food for an active, healthy life for all household members"(pg.304) is an issue for one out of six Americans [22]. According to the United States Department of Agriculture, 12% of U.S households were food insecure throughout 2015 while in Latino households 19% were food insecure [23]. People living with diabetes who are food insecure are disadvantaged in many dimensions of self-management as they struggle to stretch their budgets to purchase diabetes appropriate foods, which are more expensive than low cost calorie rich foods [24]. Thus, food insecurity often contributes to poor glycemic control and diet non-adherence [24]. Unfortunately, many medical providers fail to recognize this issue and attribute patient's inability to carry out dietary recommendations to a lack of compliance [25].

Language barriers and lack of provider-patient language concordance constitute another important barrier for many Latinos [26]. Latinos are more likely than other ethnic groups to report Limited English proficiency (LEP) with 39% reporting LEP[26]. Furthermore, nearly half of the California Latino population, living with diabetes, are patients with LEP [26]. According to Fernandez and colleagues [26], LEP is an independent and significant predictor of poor glycemic control among Latinos with diabetes. Furthermore, this association was not observed when there was concordance between medical providers and patients. Thus, language concordance is of primary importance in reducing health disparities in diabetes outcomes.

Latinos are less likely to access DSEMS; a recent study found that 59% of Caucasians report access to DSEMS compared to only 46% of Latinos [27]. Disparities are also evident across the education gradient, where 63% of those with two or more years of college education reported receiving DSEMS compared to 41% of those with less than a high school education[27].

Cultural Considerations

Over the last two decades there has been ample research on Latino cultural dimensions. Four major cultural components to be considered in the development of an intervention are "respeto"/power distance (respect), "simpatia" (formal friendliness), "familismo" (familialism) and "time orientation" (orientation to time)[28] .

Power Distance/Respeto (Respect) is an important cultural value among Latinos. It refers to the measure of interpersonal power and influence that exist between two individuals [29]. In cultures with high power distance, like Latinos, the maintenance of personal respect (respeto) allows individuals to feel acknowledged [29]. This is of particular importance in new relationships and in interactions with strangers. Thus, "respeto" is the belief that an individual is expected to defer to those who are in a position of authority because of age, gender, social position, title, or economic status. Healthcare providers are viewed as authority figures. Thus, Latino patients will tend to demonstrate "respect" in healthcare encounters. Patients might be hesitant to ask questions or raise concerns about medical recommendations, being fearful that doing so might be perceived as disrespectful. Latino patients might nod to demonstrate careful listening and respect when a medical provider is talking and yet not "comply" with treatment recommendations [28].

"Respeto" is, however, reciprocal and expected from healthcare professionals. It is important to approach Latino patients in a formal manner, using appropriate titles of respect (Senor [Mr.] and Senora [Mrs.] and appropriate greetings [good morning or good afternoon]. This is especially true with older Latinos and new immigrants [28]. U.S. White Americans tend to be highly informal, which signals a collapse of status differences and might be interpreted as disrespectful by Latino patients.

Simpatía, which means friendliness has been described as a cultural script that emphasizes the need to have smooth and pleasant relationships [29]. A person who is "simpatico" strives to behave with respect and to achieve harmony in all interpersonal relationships[29]. The implication for medical providers is that it is of primary importance to establish a positive relationship with Latino patients. While the current primary care system is time and task-oriented. Latinos tend to be more focused on relationship, than on tasks or attainment of goals. Latinos expect that healthcare providers demonstrate simpatía or "formal friendliness." Latinos may read the neutral or business-like affect of western medical providers as negative or dismissive. If the provider seems hurried, detached and aloof, Latino patients may be dissatisfied with care. This of course reduces the primary care provider's (PCP) ability to work collaboratively with patients. Engaging Latino patients is more likely if providers are attentive, take their time, show respect (greeting formally), and communicate in their native language, if possible. Physical gestures such as handshakes or even placing a hand on the shoulder help to communicate warmth [28].

"Familismo" (Familialism) has been defined "as a cultural value that involves individuals strong identification with and, attachment to, their nuclear and extended families, and strong feelings of loyalty, reciprocity, and solidarity among members of the same family" (pg. 12)[29]. A strong emphasis is placed on family as the major source of one's identity and protection against the hardships of life. Generally the family model is an extended one including grandparents, aunts, cousins, and even people who are not biologically related, referred to as "comadre" or "compadre", who are close family friends and given the status of relatives. When "familismo" is embraced, one can expect that decisions and behavior of each individual in the extended family are based largely on pleasing the family. The individual seldom undertakes

health decisions without consulting the family. Failure of the health care team to recognize "familismo" can potentially lead to conflicts, non-compliance, dissatisfaction with care, and poor continuity of care. "Familismo" can delay important medical decisions because extended family consultation can be time consuming. To gain the trust and confidence of the Latino patient, it is important to solicit opinions from other family members who may be present and to give ample time for the extended family to discuss important medical decisions. This includes decisions about action plans and SMART goals[7]. A patient may be hesitant to make a plan without first consulting or considering their family. Additionally, research has found that "familismo" can positively affect motivation for behavior change[29].

Anthropologists have documented differences across cultures in terms of temporal orientation [29]. Certain cultures, like mainstream U.S. culture, are future-oriented and emphasize efficiency and punctuality. Others, such as Latin culture, are present-oriented and value relationships rather than efficiency and punctuality[29]. It makes sense that a culture tolerant of uncertainty tends to have a relaxed attitude towards time. Many Latinos treat time as flexible and do not value punctuality the way their healthcare providers may expect them to. This explains a tendency for Latino patients to show up late for healthcare appointments fully expecting to be able to see their provider. Similarly, Latinos are accepting of certain levels of chaos and do not expect orderly processes. The western medical model, with its focus on data gathering and tracking, and its insistence on adhering to specific appointment procedures, may seem unduly regimented to less acculturated Latinos, especially those who are new immigrants.

Stage 2: Preliminary Adaptation Design

[7] SMART Goals are used in DSMES as a tool for behavior change. They are goals that are specific, measurable, attainable, and realistic and have a specified time frame.

In this stage, the information gathered in stage 1 is integrated and informs the design and modifications to be implemented. The vast majority of research on the effectiveness of SMA for diabetes has been in the Department of Veteran Affairs (VA) [8, 30]. Based on this research the VA has published a comprehensive guide to SMA implementation for diabetes [31]. The VA Model has a specific set of areas that are recommended for consideration during the planning phase (Table 2). Name them

Thus, the next stage of the ALDEA SMA adaptation process involved preliminary adaptation to the design using the Shared Medical Appointment Model delineated by the VA [31]. The preliminary adaptation design was informed by the structural and cultural issues identified in stage 1. Thus, in the next three stages (2-4) cultural adaptations will be described in two major areas: program operation and intervention content. Additionally, cultural issues will be described.

The ALDEA SMA program had the following operational characteristics. First, an open rather than closed enrollment was chosen. This decision was based on the knowledge that flexibility is important for people who lack control of their work schedule, lack transportation or are culturally inclined to not plan ahead [29]. An open continuous enrollment allowed for flexibility and the ability to attend when their schedules permitted. As the aforementioned literature indicates, Latinos tend to dislike rigid schedules [29]. Additionally, patients were informed that they could arrive late if necessary to encourage attendance and reduce the barrier of punctuality.

Most SMA programs have counted on abundant resources and had extensive multidisciplinary teams [30]. The ALDEA SMA program was created with the mission of providing access to DSMES to uninsured patients and thus limiting costs was essential. In

order to achieve this goal, we designed a team that was led by a family nurse practitioner (FNP), FNP students, a medical assistant, an administrator and community volunteers. This team composition lowered costs and increased the potential for sustainability of the program. Furthermore, all team members were bilingual and bicultural in an effort to remove communication barriers. This was of importance given the literature on the importance of patient and provider concordance on glycemic outcomes [26]. Initial enrollment and outreach relied on referrals from primary care providers, the clinic diabetes registry, phone outreach (Appendix A) and culturally tailored flyers (Appendix B).

In order to address some of the structural issues identified in stage 1, a sliding scale was established for uninsured patients and health literacy and food insecurity screening questions were incorporated into the SMA clinical form (Appendix C).

A critical adaptation in the ALDEA SMA program relates to the underlying philosophy of empowerment theory. Thus, ALDEA adopted the philosophy put forth by Funnel and colleagues [32], which was " the purpose of empowerment based care and education is to enhance autonomy and enable the patient to make informed decisions, solve problems and achieve self-determined behavioral goals" (pg.1991).

Following an empowerment philosophy, the curriculum of ALDEA was developed in collaboration with the patients. Providers and patients collaborated to define the topics and activities for each session. The lead nurse practitioner used the framework of the American Association of Diabetes Educators (AADE) 7 Self Care Behavior Topics [33] and the American Diabetes Association (ADA) National Standards for Diabetes Self-Management Education [6] to guide the process. Thus, the curriculum was fluid and was developed based on a collaborative process among all members of the group.

We anticipated that Latino patients with low literacy, low numeracy, and/or linguistic needs might experience challenges in understanding diabetes information and applying concepts to their self-management [21]. The vast majority of diabetes education materials are not designed for people with low health literacy [34]. After reviewing available patient education materials the American College of Physicians Foundation's Living with Diabetes Guide [35] was chosen because it was designed for patients with low health literacy and numeracy, and developed to include ethnic specific foods for Latinos.

Additionally, the PRIDE toolkit developed by the University of Vanderbilt was used as the basis of educational activities and group interaction. The PRIDE toolkit was designed for patients with low health literacy and numeracy in English and Spanish [34]. The toolkit is sensitive to patients' literacy and numeracy levels, language preferences, and cultural norms. Moreover, it encourages shared goal setting to improve diabetes self-management and health outcomes [34]. Materials from the American Diabetes Association were also used when deemed appropriate. For example, the handout on interpreting nutrition labels.

Stage 3: Adaptation Test

This stage consists of conducting a process evaluation and pilot testing the intervention. The process evaluation assessed the program's operations, intervention content and unanticipated cultural issues or structural barriers to care. We chose a participatory approach congruent with empowerment. Thus, both the patient and the medical team were active participants of this continuous process.

The first ALDEA SMA group started in January 2015 and was held on Friday mornings. This day and time were chosen based on pragmatic agency factors including the availability

of a conference room and afternoon preceptor for the nurse practitioner student who was an essential team member. A total of 15 patients were enrolled within the first 6 months. Patients were recruited with flyers, primary care referrals and outreach phone calls to those in the clinic's diabetes registry with HbA1C above 9%. The 15 patients of the first cohort were recruited within the first three months of the program.

Attendance was consistent, with an average of 6 patients attending group each week. the average number of SMA visits attended by patients during the first year was 17. The major barriers to attendance reported by patients were conflict with work schedule and lack of childcare. Enrollment of new patients became challenging when the patient was not an established patient at the clinic. This was not anticipated and there was no procedure within the group for new patient registration.

The staffing of the groups relied heavily on volunteers and nurse practitioner students. Every three months students and volunteers would change since they were following the academic quarter calendar. Feedback from patients was clear that changes in personnel were difficult and they would prefer to have consistent support staff. Fortunately, the team had a nurse volunteer and an administrator who were permanent. Additionally, during the first 6 months there were 2 or 3 nurse practitioner students per SMA group. While the support of the students was beneficial to group facilitation this number of students turned out to be a burden for the lead nurse practitioner and thus the number of students was lowered to one per session.

For the first year of operation the SMA had an intermittent and rotating medical assistant who was not specifically trained in the operation of the SMA and had no unique knowledge

of diabetes. This presented a challenge when support for the group leader was needed with lab orders or referrals.

To address two structural issues identified earlier, namely financial barriers and food insecurity, free diabetes supplies (glucometers, test strips, glucose tablets)were provided as much as possible via donations from industry. A food distribution site was established at ALDEA where the SMA took place. The food consisted primarily of fruits and vegetables, which were offered free of cost twice a month at the health center, were the groups were held.

Patients in collaboration with the ALDEA team defined the content of the intervention weekly. Patients actively participated in determining the topics to be covered and designing the activities for the group to engage in. Appendix D lists some of the topics covered and activities selected. Of interest was how often patients requested not to have an agenda and preferred a "la volada" ("wing it") approach. Some of the richest sessions were unstructured, allowing patients to share experiences, ideas and fears, and to ask questions freely. Additionally, activities that involved cooking and sharing food were among participants' favorite activities. Lastly, short zumba sessions (10 minutes) were often requested to start the group.

The education materials chosen during the preliminary intervention design proved to be quite effective for this patient population. Patients reported liking the Living with Diabetes Guide and referring to it often. They especially liked that the guide provided them with pictures of correct portion sizes rather than just numbers. An area of challenge was the lack of availability of evidence-based Spanish educational videos for low health literacy patients. Thus, the Internet was used as a resource and a variety of videos were chosen. Patient

feedback was used to guide the choice of videos in future sessions. The most well liked videos were those produced by a Peruvian medical doctor. This was a series of short programs produced in Peru for a television show. They are available as YouTube videos and most are 10 minutes long. These videos were perhaps popular with participants because they are presented simply and in a format that is entertaining [36].

The cultural considerations identified in the formative stages were deeply immersed in how the program was delivered. For example, respect was provided in a culturally appropriate way by greeting each participant formally when they arrived to the group. This varied depending on the sex of the participant and the depth of the relationship with the team. Women and men were initially greeted by a formal handshake and greeting. Over time, women were greeted with a kiss on the cheek or a hug following patient's cues. This is normative behavior in Latin America and one that marks respect and warmth. Over time, greetings for men remained more formal with a handshake, but rarely with a kiss on the cheek, which is also normative and communicates respect.

As previously mentioned, Latin American culture is one were power distance is high, and thus those with less power (the participants) will unlikely voice a different opinion or raise questions to those with more power (the medical team). The ALDEA SMA team chose to address this in a direct manner by openly discussing this power dynamic in traditional medical encounters in Latin culture. We then explained that the nature of the ALDEA SMA program was one that emphasized collaboration and encouraged all members to participate and voice their concerns and questions openly. We emphasized that in order to achieve our goals of improved diabetes care and long term health, participants and medical providers

needed to collaborate and respect each other. The concept that people living with diabetes were the experts was emphasized routinely.

Another cultural component that needed to be considered is that of "simpatia". It was important to remember this concept in how group processes were handled by the group facilitator. As mentioned earlier, "simpatia" strives to achieve harmony in all interpersonal relationships. Thus, in facilitating group processes in the ALDEA SMA program it was important to communicate in a way that avoided direct disagreement with a patient. Rather we gently redirected the conversation, and found a way to address the issues indirectly thus avoiding public disagreement. These efforts prioritized "simpatia" and communicated in a culturally sensitive manner, which was friendly, non-direct, and respectful.

The importance of family had to be prioritized over rules and regulations. Although as a rule children were not invited to the group, patients agreed to allow children in the group on an as needed basis if childcare was a barrier to participation. Participants were respectful in not abusing this privilege, only bringing young kids when absolutely necessary and leaving the group if they became disruptive. Additionally, "familismo" was acknowledged and respected in the process of behavioral goal setting by acknowledging and allowing time for participants to process decisions with family. For example, one patient wanted to set the goal of not purchasing regular sodas for home consumption. She felt she must consult with her husband and have his support before she could commit to this plan.

Another important cultural consideration was that of time orientation. This was addressed by providing flexibility with time. Many patients, some due to work or bus schedules, others because being on time was not a priority, arrived 10-15 minutes late to group. Patients were asked to arrive as close to on time as possible, but also were told that arriving late was

acceptable and preferable to not coming due to tardiness. Patients who arrived late and could not have their vital signs and individual visit/check in with the medical provider at the beginning of the group, as planned, were met with open arms and flexibility rather than with reprimand and disappointment. This part of their visit was completed at the end of group. Thus, ALDEA provided and required flexibility.

There were two major unanticipated issues that surfaced, likely due to the strong and safe relationship established between the medical team and patients. The first relates to the extensive use of traditional herbal medicines. The medical team normalized the use of herbs by asking directly for names of herbs used during medication reconciliation, as a way of encouraging patients to share that information. The group became a place were patients freely shared advice and names of herbs and supplements. The lead nurse practitioner did not have expertise nor training in herbal medicine, but patients relied on community providers or family knowledge to structure herbal remedies. The second issue related to transportation as a structural barrier for patients. It was noted that attendance was lower during the winter months. Many patients relied on public transportation, or walking, to get to the clinic and during inclement weather in the winter this became a barrier to attendance.

4. Adaptation Refinement

In this stage information gained from the previous stages was integrated and further adjustments were made to the preliminary adaptation.

After the first year of operation a second evening group was implemented in order to provide access to working people and to those who lacked childcare during the day. An evening group also addressed the need to include family. To avoid the inefficiency of

registering new patients, it was decided that patients would be allowed to be guests for one visit. Then, if they chose to continue, they would have to register as a new patient at the front desk prior to the next visit. A plan was made to recruit a new medical assistant who would be assigned to the ALDEA SMA program and would be trained in all of its procedures.

An unexpected cultural issue, described earlier, was the disclosure over time of the widespread use of herbal medicines among patients in the ALDEA SMA program. Questions about herbal use were integrated in medication reconciliation (Appendix D). Communication was clear and open between patients and team members. Patients discussed herbs used with the group and the lead NP researched interactions and safety. This information was then shared with patients at the following meeting. Patients were eager to learn about the efficacy and safety of herbs and freely shared information. This became a regular part of the group sessions. Some of the most common herbs used by patients from El Salvador and Mexico were moorings (horse radish tree), nopal (prikly pear cactus), tepezcohuite, tilo (thyme), changaro, guayacan, jengibre (ginger) and canela (cinnamon), ajo (garlic), avila (Aloe Vera), una de gato (Cat's claw) and valeriana (valerian). The National Center for Complementary and Integrative Health served as a resource to check for interactions and safety [37].

To address the issue of transportation patients created an informal carpool among themselves. Rides were offered and organized for the following week. Lastly, two cultural issues that were unforeseen were the lack of attendance during some Christian holidays and the discovery that mindfulness meditation was not culturally appropriate for Latinos who belong to the Jehovah's Witness Church. Consequently, groups were scheduled less

frequently during the holidays and mindfulness exercises were avoided when members of the Jehovah's Witness Church were present in the group.

Stage 5: Cultural Adaptation Trial

This stage consisted of an empirical trial on the effectiveness of the cultural adaptation model. A six-month study was conducted to determine the effectiveness of the culturally adapted ALDEA SMA program as compared to usual primary care (UPC) for adult Latinos with type 2 diabetes. The outcome measures assessed in this quasi-experimental matched-controlled study were HbA1C, Low Density Lipoprotein (LDL) and blood pressure at baseline, 3 and 6 months. The results from this study will be published in a separate paper.

Conclusion

Castro's (2010) four-stage cultural adaptation model, which infuses culture into health interventions, provided a framework to design and evaluate process outcomes of the ALDEA SMA program. A number of reviews and meta-analyses have concluded that culturally adapted interventions for ethnic minority populations were more effective than standardized, non-culturally adapted programs [38]. A review of culturally sensitive nutrition and exercise interventions among Latinos reported three main intervention features that appeared to be associated with successful interventions: involvement of family and social support, literacy level appropriate materials and methods and cultural values [39]. The ALDEA SMA model successfully incorporated important cultural components and provides some guidance for future SMA implementation in the Latino community.

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Table 1

Cultural Adaptation Stages: Elements addressed in ALDEA SMA

	Stage 1: Information Gathering	Stage 2: Preliminary Intervention Design	Stage 3: Adaptation Test	Stage 4: Adaptation Refinement
Structural Issues	Low SES/Insurance status Low Health Literacy (LHL) Food Insecurity (FI) Language Barriers	Sliding fee scale Screening for HL LHL education materials adopted Screening of FI Bicultural and Bilingual Staff	Sliding fee scale Low cost pharmacy Low cost/free diabetes supplies Food distribution established on site	LHL screen integrated into EMR intake form FI screen integrated into EMR intake form
Cultural Issues	"Respeto" "Familismo" "Fatalismo/Time Orientation"	Training of staff about Latinos cultural norms Family members invited to participate Flexible schedule, late arrival normalized		
Program Operation	Closed vs. Open Group Time limited vs. Ongoing SMA Team/staff	Open Ongoing Morning group Lead NP FNP student (2) Volunteer RN Volunteer Administration/host	Open Ongoing Morning group FNP student (1)	Evening group implemented Medical Assistant hired for SMA

Intervention Content		Empowerment Patient driven agenda LHL "Living with Diabetes guide" adopted LHL PRIDE Toolkit adopted	LHL educational videos identified	
Unanticipated Cultural Issues			Herbal Medicine Transportation difficulties during Winter Low attendance during Christian Holidays Mindfulness Meditation (MM) not acceptable to members of Jehovah's Witness (JW) Lack of agenda desired sometimes	Herbal Medicine integrated into EMR intake form Informal carpool established Schedule adjusted during holidays Religion incorporated to intake form Avoided MM when JW members were present

Table 2

Veteran Affairs SMA Planning/Developmental Phase Guideline

Type of Group	Open vs. Closed
Health Care Team	Multidisciplinary
Criteria for Eligibility	High Risk, Lack of DSME
Patient Identification	Registry and referrals
Enrollment Strategy	Schedule/letters and Reminder Calls
Frequency and Duration	Weekly, Ongoing
Patient F/U	PRN
Length	120 minutes
Structure of sessions	30 min individual check in 15 minute introductions 45 min group activity 30 min wrap up, planning
Number of patients scheduled	20
Expected # to attend	10
Confidentiality Rules	Each time
Space requirements	Conference room and private exam room

Appendix A

Protocol for Phone Outreach

This document to serve as a protocol for new potential outreach Participants for evening SMA and UCSF research project.

Good morning Mrs. ----------. My name is ---------, I call to invite you to a program that the clinic is offering for people with diabetes. The program has been conducted over the last year and has been very successful. We are now starting a new group that will take place on Monday at 530pm at The Family Clinic East Cliff. The program consists of a shared medical appoinment for people with diabetes. Unlike an individual medical appointment, this program offers shared medical appointments. This means that you can receive individual attention from yourdiabetes, including laboratorie orders and medication refills, in addittion to other services . The biggest difference is that in this group appointment you will have accesso to the medical team for a total of two hours. During this time, there will be educational sessions, cooking activities, exercise, and many other hands on ctivities to help you achieve control of your diabetes. Besides medical care, and education, you will also receive support from others who are living with diabetes. The group is carried out every week and you can choose how often you want to attend, either every week, once a month or whatever is best for you. The cost depends on income and medical pays for them.

For the study portion: to be introduced after questions regarding the SMA are answered .

The other opportunity that would like to share with you, is the opportunity to participate in a study carried out by the person who runs the group, Carolina Noya. The purpose of this study is to assess how effective this program is to help you gain control of your diabetes and improve the quality of life for patients. Participation in the study requires filling out a survey and we will provide support if needed. Participation in the studyis not mandatory. You can choose particiapate in the group and not in the study. If you wish to consider being part of the study, director of the group will provide more information on the first day of the group .. To thank you for your time, there will be food and drinks available. Do you have any questions?

Appendix B

FLYER

CLÍNICA DE DIABETES

A PARTIR DE ABRIL VAMOS A FORMAR COMUNIDAD! GRUPO NUEVO EN LA NOCHE!

Grupos clínicos para personas con diabetes y su familia. Reciba su cuidado médico, educación y recursos con un grupo de 10-15 personas. El grupo incluye cuidado médico, apoyo, educación y recursos para su cuidado de la diabetes.

Clínica de Diabetes

2 horas con el equipo médico! Dirigido por Carolina Noya,FNP.

Medical cubre el gasto! Bajo costo para pacientes sin aseguranza!

Compartiremos recétas saludables!

Recibirá apoyo de otras personas

SANTA CRUZ COMMUNITY CLNICS
East Cliff Family Health Center

Grupos empezarán en Enero!

Appendix C

SAMPLE OF ALDEA SMA EDUCATIONAL TOPICS AND ACTIVITIES

EDUCATIONAL TOPIC	ACTIVITY	COMMENT
Nutrition	• Cooking traditional recipes • Sharing recipes • Analyzing food plates • Adapting culturally specific foods to reduce carbohydrate • Dr. Peru videos • Eating healthy on a budget • Creation of healthy "licuados"	Sharing traditional dishes was a favorite activity. Patients brought favorite foods and we deconstructed recipes and made suggestions for keeping it authentic, but healthier.
Exercise	• Zumba and walking. • Resistance training program during "novela" time	Short sessions of zumba were often how groups chose to start sessions. We all danced together. Resistance training during "novella" time was a simple way of incorporating exercise into daily routines.
Foot Care	• Foot exam at the beach	Many patients, who were self conscious about their feet, especially if they worked in agriculture, enjoyed washing their feet in the ocean prior to exam.
Eye Health	• Educational Videos	
Medical Management	• Adherence- trip to dollar store to buy pill boxes • Labeling of pill boxes with pictures for low literacy patients • Insulin Therapy- educational and practical session	Difficulty with labels/instructions on medication bottles was common due to low health literacy. Labeling bottles with pictures was a common and successful strategy.
Psychosocial and Behavioral Support	• Problem Solving and SMART Goals developed throughout the year • Depression screening and referral • Diabetes distress, story telling hour • Immigration trauma and family separation • Mindfulness Meditation	Immigration trauma and distress was often discussed although never formally planned.

Shared Medical Appointments: An Innovative Model to Reduce Health Disparities Among Latinos Living with Type-2 Diabetes ALDEA: Latinos con Diabetes en Acción

Introduction

Diabetes has grown exponentially over the last three decades it has reached epidemic proportions in the United States (U.S.). An astounding 29.1 million people or 9.3% of the U.S. population is currently living with diabetes [1]. Moreover, disparities in diabetes morbidity and mortality rates among racial and ethnic minorities continue to exist. Non-Hispanic Whites have the lowest incidence (7.6%), followed by Asians (9%), Hispanics (12.8%), Non-Hispanic blacks (13.2%) and American Indians/Alaskan Natives (15.9%)[1]. Health disparities have been documented with fewer Latinos, African Americans and Native Americans diagnosed with diabetes receiving standard diabetes care, such as immunizations, foot examinations, ophthalmology screenings, and diabetes education, compared to their White counterparts [2].

According to the American Diabetes Association (ADA), Diabetes Self-Management Education and Support (DSMES) is a cornerstone of standard medical care for adults with diabetes [3] [4]. Unfortunately, despite the proven efficacy of DSMES [2], only half of adults with diabetes reported ever receiving formal diabetes education or attending self-management classes [4]. Furthermore, patients who do attend a diabetes self-management class often receive basic information and lack adequate support (Lorig & Gonzalez, 2000). Others receive the majority of their education from their primary care providers, however, most individual visits with a medical provider are problem-focused and do not allow enough time for education or behavioral interventions [5, 6]. In response to this gap in standard medical care for adults with diabetes, the ADA (2013) called for change in delivery of care to improve diabetes management and outcomes. According to the ADA, "a major barrier to optimal care has been a delivery

system that is fragmented, lacks clinical information capabilities, duplicate services and is poorly designed for coordinated delivery of chronic care"(pg.57) [3]. The Chronic Care Model has been shown to be an effective framework to improve diabetes care, and Shared Medical Appointments (SMA) constitute a type of delivery system redesign that is proactive where planned visits are coordinated for a group of patients with a multidisciplinary team. [6, 7]

Shared medical appointments are an increasingly popular educational and supportive primary care service aimed at improving access to DSMES and primary care services in order to improve diabetes self-management and decrease diabetes related complications [8-12]. Shared medical appointments are a promising alternative to individual office visits because they can integrate DSMES and peer support within the primary care visit. They also nurture collaborative relationships between providers and patients, while group activities refine disease management skills and enhance knowledge [13]. The strategies used in SMAs are rooted in self-efficacy theory and promote collaborative goal-setting in the form of behavioral "action plans" [14], wherein patients set short-term self-management goals in collaboration with their primary care provider.

Over the last 15 years, research on the effectiveness of SMAs to improve diabetes outcomes has emerged, and there is sufficient evidence on the effectiveness of SMAs on HbA1C and blood pressure to support the implementation of SMAs among White adults with type 2 diabetes [8, 13]. Unfortunately, the current literature on SMA effectiveness has, for the most part, excluded monolingual Spanish speaking Latinos [15]. Gutierrez and colleagues (2011) reported a mean Hemoglobin HBA1C (HBA1C) decrease of 1.19% in SMA group vs. 0.67% for control group ($p=0.02$) among Spanish speaking Latinos in a residency clinic. To our knowledge this is the only randomized controlled trial (RCT) to include low income, uninsured Latinos.

Thus, at this time there is a need to expand the research on the effectiveness of SMAs to Spanish speaking Latinos living with type 2 diabetes. The study of SMAs as an innovative model of care for uninsured/underinsured Latinos has the potential to identify a sustainable and effective model of care to reduce health disparities.

Purpose of Study

The purpose of the study was to evaluate the effectiveness of a nurse practitioner led intensive behavioral SMA intervention, referred to as ALDEA (Latinos con Diabetes en Acción), compared to standard or usual primary care (UPC) for the treatment of persons with type 2 diabetes and associated cardiovascular risk factors over a 6-month period. Cardiovascular risks were HBA1C, low-density lipoprotein (LDL) and systolic and diastolic blood pressure (BP). The primary outcome was HBA1C. Secondary outcomes were LDL and systolic and diastolic BP.

Hypotheses:

1. SMA participants will have a larger mean change in HBA1C compared to UPC participants at 6 months post-intervention.
2. There will be a greater percentage of SMA participants with normal LDL (< 100 mg/dl) compared to UPC participants at 6 months post-intervention.
3. There will be a greater percentage of SMA participants with normal BP (<140/80 mm/Hg) compared to UPC participants at 6 months post-intervention.

Methods

Research Design

This study was a quasi-experimental design with a non-randomized matched control group that followed participants prospectively for 6 months. The intervention group and control

group had a ratio of 1:2 participants. The Institutional Review Board at the University of California San Francisco approved the study, including the protocol and consent forms. Study enrollment began on January 2015 and ended October 2016.

Sample

All adult, 18 years and older, Spanish-speaking Latinos living with type-2 diabetes receiving primary care at a Federally Qualified Health Center (FQHC) clinic were eligible for inclusion in the study. Participants of the SMA intervention were included if they met the following inclusion criteria, had HBA1C >9% (75mmol/mol) and/or lacked access to diabetes education and support outside of primary care visits, and attended a minimum of three SMA sessions. Participants in the control group were matched concurrently on baseline HBA1C and age. Patients were excluded if they had a disability that impeded their capacity to participate in group activities. Patients were referred by their primary care providers, recruited via flyers and phone calls using the diabetes registry at the SCCHC. A total of 55 potential participants were approached to participate in the ALDEA SMA program and 40 chose to participate. Of those who chose who participate, 10 were excluded because they attended less than 3 SMA's, leaving an intervention group of 30. Participants who chose not to participate reported lack of childcare as the main barrier to participation (70%).

The non-probability convenience sample consisted of 90 participants receiving primary care at a FQHC clinic. Thirty participants comprised the SMA intervention group, enrolled as two cohorts. The first cohort consisted of 18 participants and was used to determine the effect size for the study. The second cohort consisted of 12 participants. The control group was a non-random, matched group of patients receiving UPC at the FQHC clinic. At baseline, intervention and control group participants were matched by age (within 5-10 years) and HBA1C levels

(within 0.5-1%). Additionally, each cohort was matched with their control in time with their control so that baseline and follow-up data mirrored each other. Based on results from the first cohort intervention group, the study was powered at 80% to detect a mean change difference of 1.48% or 0.1 mmol/mol in HBA1C at 6 months between the intervention and control groups. To achieve this mean change difference (medium effect) at $p \leq 0.05$, two-tailed, the a priori sample size calculation indicated a total minimum sample of 84.

ALDEA Shared Medical Appointments Intervention

Latinos con Diabetes en Acción (ALDEA), a culturally tailored SMA program, was developed and implemented in the Spanish language at a single FQHC site [8]. The structure of the SMA intervention was based on the model refined by the Veterans Affairs Office [11]. In this model, groups include peer support, DSMES with a focus on behavioral approaches (SMART goals and problem solving) and medical management. SMART goals are specific, measurable, agreed upon, realistic and time-based. The ALDEA SMA program team consisted of a lead family nurse practitioner (FNP), an FNP student, a medical assistant and a volunteer registered nurse. All of the team members were native Spanish speakers and bicultural.

The ALDEA SMA program had an open enrollment policy, were participants cold join at any given time, and groups were limited to 12 patients per group. The intervention was offered once a week for two hours on an ongoing basis. Initially only one morning group was offered with the additional evening group in the second year of operation. In the second year, participants had the choice to attend the morning or evening sessions. Participants were invited to attend the SMA intervention as often as they wished during the six-month study period. The

[8] A separate manuscript will be published describing the cultural adaptation of the SMA program.

SMA sessions used a group process to provide support, education and patient activation. Motivational interviewing (MI) [16] and group processes were used to promote collaborative goal-setting and problem-solving in the form of individual action plans and were integrated into individual visits/check-ins as well as group activities. The individual component included the following: patient registration, vital signs, medication reconciliation and individual assessment of diabetes management (laboratory findings, orders, medication refills, medication titration, review of SMART goals and action plans, and referrals).

The content of the SMA sessions was participant-driven. In other words, participants decided every week what content and activities they wished to engage in the following week. Activities included, but were not limited to, didactic sessions, hands on experiential learning, exercise, group discussions, recipe sharing and cooking activities. During individual visits/ check-ins, the medical provider reviewed and revised SMART goals in collaboration with each participant. During this time, the provider engaged in problem solving as necessary to explore barriers and define new goals. Similarly, during group education, interaction or activities, the group engaged in problem-solving in relation to their treatment barriers and the topic being discussed, and supported each other in goal-setting.

Participants in the ALDEA SMA intervention group attended an average of 13 appointments during the first six months of the program.

Usual Primary Care

The UPC group participants received the clinic's standard of care for persons with diabetes. Standard of care consisted of quarterly individual clinic visits with a primary care provider (i.e., MD, FNP or PA) of approximately 20 minutes. Referrals to DSMES were made

routinely as part of standard of care. There were no dieticians or diabetes educators available onsite.

Measures

Demographic variables were obtained from the medical records of intervention and control group participants, as were laboratory values of HBA1C, systolic and diastolic BP and LDL.

Demographic variables:

The following demographic data were collected at baseline: chronological age (in years), number of diagnosed chronic diseases, , poverty level (defined per federal guidelines), and health insurance (yes or no for any type of comprehensive insurance, public or private payer).

Outcome/metabolic variables:

Hemoglobin HBA1C. The primary outcome, HBA1C, was measured with a high performance liquid chromatography method used by the Bio-Rad Hercules laboratory. Data were obtained at baseline and 3 and 6 months. If a participant had more than one measurement in a 90-day interval, the average of all HbA1C levels collected during the interval was used. Hemoglobin HBA1C levels obtained within 24 hours of the first SMA appointment were considered to be pre-SMA baseline data. Post-SMA data points were calculated as time from first SMA appointment. Data from all participants were then aggregated based upon corresponding time intervals every 3 months. Quarterly measures of HBA1C are part of the ADA guidelines of care for people with diabetes. Normal HBA1C is <7% or 53mmol/mol. Baseline HBA1C levels were based on clinical significance and categorized as high (HBA1C ≥ 10% or 86 mmol/mol), medium (HBA1C 8-10% or 64-86 mmol/ml) or low (HBA1C 6-8% or 42-64mmol/mol).

Low-density lipoprotein. Laboratory data for LDL was extracted from all of the participants' electronic medical records 6 months. The value of the last LDL, closest to the 6-month post-intervention data collection point, was utilized. Per current guidelines, LDL variable was dichotomized (yes/no) as to whether the participant achieved the recommendation of <100 mg/dL[17]

Blood pressure. Both systolic (SBP) and diastolic blood pressure (DBP) were measured using calibrated manual cuffs, taken by a medical assistant or nurse practitioner student at each visit. Blood pressure values closest to the 6-month time post-intervention data collection point was used for analysis. Per current guidelines, the BP was dichotomized (yes/no) as whether the participant achieved the recommendation of <140/80 [17].

Data Analysis

Data entry and statistical analyses were conducted using SPSS 19. Descriptive statistics were used to summarize the data and identify outliers. Differences in the demographics and study variables between the intervention group and the control group were calculated using Student's *t*-test for independent groups and chi-square and Fisher exact tests, depending on the level of data. Differences in the demographic characteristics between groups were compared only at baseline. Differences in HBA1C between groups were compared at baseline and 3 and 6 months. Differences in the percentage of participants in each group who achieved HBA1C, LDL, BP and all three target goals, per the previously described ADA guidelines, were compared at 6 months [3]. Differences in the percentage of participants in each group who achieved the HBA1C target was also compared at 6 months. Lastly, to evaluate the impact of missing data, differences in baseline demographics and HBA1C was compared between participants with compete and missing data.

To test the effect of group membership on HBA1C change, differences in change scores were compared between the ALDEA SMA intervention group and the UPC control group. Linear regression analysis was computed to assess if mean HBA1C change at 6 months post-intervention was greater among SMA intervention group participants compared to the UPC control group participants.

Post-hoc analyses were conducted to examine trends of HBA1C change stratified by baseline HBA1C values in the intervention and control groups. Baseline HBA1C levels were based on clinical significance and categorized as high (HBA1C ≥ 10% or 86 mmol/mol), medium (HBA1C 8-10% or 64-86 mmol/ml) or low (HBA1C 6-8% or 42-64mmol/mol). Mean change values at 3 and 6 months were then calculated for each of the baseline clinical significance HBA1C categories (high, medium or low) for each group.

Results

The mean age of the sample was 53.36 years. The mean poverty level of the sample was 96.35 of the Federal Poverty Level or less than 23,328 for a family of four, 61% had health insurance and the mean number of diagnosed chronic conditions were 2.36 (see Table 1). There were no significant differences at baseline between ALDEA SMA intervention groups A and B in terms of age (p=.35), poverty level (p=0.54), number of chronic conditions (p=0.43), or insurance status (p=0.33). Consequently, intervention groups A and B were combined for the remaining of the analyses. Table 2 shows sample sizes and missing data for HBA1C at 3 and 6 months. There were no statistically significant differences on demographic variables or baseline HBA1C between those with complete or missing data,

There were no statistically significant differences in age (p=.27), poverty (p=0.18), health insurance status (p=0.35) and comorbidities (p=0.69) at baseline between the intervention and control groups. Additionally, at baseline, blood glycemic profiles were not statistically different between the intervention and control group, although the mean HBA1C was slightly higher in the intervention group (9.97± 2.42) compared to the control group (9.43 ± 2.06) [t=1.093, p=.25]. A greater percentage of intervention group participants (58.6%) than control group participants (31%) achieved target HBA1C goals at 6 months post-intervention (χ^2= 4.462, p≤ 0.05). See Figure 1.

The reductions in HBA1C were greater in the intervention group relative to the control group at 3 months (-1.69% vs. –0.59%, t= -2.156, p≤0.05) and at 6 months (-1.48% vs. -.241%, t=-2.458, p≤0.05). See Figure 2. Compared to the control group, results of the linear regression analysis revealed that there was a net reduction HBA1C difference of -1.09% from baseline to 3 months (p≤0.05) and -1.23% from baseline to 6 months (p≤0.01) in favor of the intervention group. The majority of participants in the intervention group (90%) and in the control group (88.5%) had on-target BP values at 6 months (χ^2=.045, p=.832). Sixty-five percent of intervention group participants compared to 50% of control group participants had on-target LDL values at 6 months (χ^2=1.66, p=.198). See Table 2. Lastly, 32% of intervention group participants compared to 14.8% of control group participants achieved the on-target goals for all three criteria (HBA1C, LDL and BP) (χ^2=2.83, p=.24). See Table 1.

Post-hoc analysis of HBA1C change trends, stratified by baseline HBA1C clinical significance categories (high, medium and low), revealed that intervention group participants had a downward trend in HBA1C across the 6-month period, regardless of baseline value (see Figure 4). In contrast, there was not a downward trend in HBA1C across the 6-month period, regardless

of baseline value, for control group participants (see Figure 3). In other words, participants in both the control and intervention groups with high baseline clinically significant HBA1C values improved over time. Only intervention group participants with low and medium baseline HBA1C, however, showed improvements in HBA1C across the 6-month period. Their counterparts did not show improvements in HBA1C across the 6-month period.

Discussion and Conclusions

To our knowledge, this quasi-experimental study is among the first to document the impact of a culturally adapted SMA model to improve glycemic control among low-income, Spanish-speaking only Latinos living with type 2 diabetes. This study demonstrated that underserved and underinsured Latinos enrolled in the ALDEA program, a culturally sensitive, community based, nurse practitioner-led, SMA model, were able to achieve HBA1C goals in greater numbers compared to those who received usual primary care. Furthermore, the ALDEA SMA intervention led to a statistically significant net reduction of 1.09% at 3 months and 1.23% at 6 months in HBA1C over the 6-month period compared to UPC participants. These results are encouraging, are of clinical significance and are comparable to findings in the literature of SMA effectiveness in reducing HBA1CFor example, . In the United Kingdom Prospective Diabetes Study, a 1% decrease in HBA1C values, translated to a 14% decrease in macro-vascular diseases, a 37% decrease in micro-vascular complications and a 21% decrease risk of deaths related to diabetes [18].

Important to note is that the prevalence of people with type 2 diabetes that meet HBA1C, BP and LDL recommendations in the U.S. vary by ethnicity [4]. Stark and colleagues (2013) analyzed NHANES data from 1988-2010 and noted that overall, between 2007-2010, recommended HBA1C was met by 52% of the sample, blood pressure by 72% of the sample and

LDL by 56% of the sample. Only 20% of the sample met the recommendations for all three criteria. Furthermore, Mexican Americans were less likely, than their White counterparts, to meet HBA1C and LDL goals, 52% vs. 46% and 62% vs. 45% respectively [4]. The ALDEA SMA participants demonstrated a higher percentage of achieving recommended goals, compared to UPC, for HBA1C (58.6% vs. 31%), BP (90% vs. 85%) and LDL (65.4% vs. 50%) and 32% vs. 15% met all three criteria. Thus, ALDEA patients achieved goals well above national trends both for Latinos and for the overall population.

Although these are novel findings, there were several limitations to the study. The lack of a randomized control group can lead to selection bias. Self-selection in the ALDEA SMA program may have favorably influenced the results. Patients who chose to participate in the SMA group may have been already and motivated to improve their health. Not-withstanding, evidence of this model provides the foundation for designing a more rigorous, prospective randomized trial in the future.

Another possible threat to internal validity was that of possible design contamination. Despite best efforts, the treatment and control groups may have influenced each other in some way. For Example, implementation of the ALDEA SMA program might have motivated medical providers to pay closer attention to the quality of diabetes management in their primary care practice. In addition, members of the ALDEA SMA program were highly motivated and enthusiastic about the program due to its novelty and being part of a dissertation. Further research is in progress in three other community clinic settings with different personnel and level of resources.

Generalizability is limited. This intervention was implemented at a single site with a relatively homogenous population of low-income, Spanish-speaking Latinos from Central

America and Mexico and it is unknown if this model could be implemented successfully in a different setting and with diverse populations. Future studies should test the efficacy of the ALDEA SMA intervention in different settings, with different populations, and with a different team composition.

Future research on the effectiveness of SMA as a model of care should attempt to close these gaps in the literature. In particular, comparative effectiveness studies are necessary to identify which components were responsible for change (diabetes education, behavioral interventions, medication titration or peer support), what frequency of visits is optimal (weekly, bi-weekly or monthly), or which types of SMA (open enrollment versus closed group) produce the best outcomes at the lowest cost. Researchers should attempt to use standardized instruments across studies that will allow for meta-analysis, and include not only biophysical measures, but also patient-centered outcomes such as self -efficacy, quality of life and patient activation/engagement. Future research should be powered to be able to examine mediating and moderating factors between the SMA intervention and improved outcomes. In other words, is patient engagement a moderating factor on the effect of SMA intervention and HBA1C outcomes? Is medication titration a mediating factor on the effect of SMA on metabolic outcomes? Is self efficacy a moderating factor?

It is important to note that unlike usual SMA teams found in the literature, this team was small and included only one health professional (nurse practitioner). The cost effectiveness of this approach is of importance as it may prove to be a cost effective approach to reach the most vulnerable and low resourced populations. More data are needed on cost effectiveness before policy recommendations can be made.

In conclusion, given the disproportionate rates of type 2 diabetes and poor outcomes

among Latinos in the U.S. [1] it is important that research with this vulnerable population continues to be developed. To date, there has been only one RCT evaluating the effectiveness of SMA with Latinos[15]. This study is the first, to our knowledge, to document the effect of a culturally tailored SMA program with low income, underinsured Spanish speaking Latinos lead by a nurse practitioner.

In conclusion, the ALDEA SMA program has been successful in empowering Latino patients and improving glycemic control. ALDEA has the potential to reach underserved communities and result in significant improvements in the health status among the most vulnerable patients.

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Table 1
Demographic and Clinical Characteristics of Study Participants

Demographic Characteristic	**ALDEA SMA (n=30)**	**CONTROL (n=60)**	**p value**
Age in years, mean, (SD)	54.87 (12.7)	51.85(12.1)	0.32
Poverty Level, mean, (SD)	83.70 (53.95)	109.00 (124.7)	0.18
Insurance Status, n, %	56.7% with insurance	68.9% with insurance	0.35
Number of Diagnosed Chronic Conditions, mean, (SD)	2.41 (1.8)	2.31 (1.14)	0.69
Clinical Parameters	**ALDEA SMA (n=30)**	**CONTROL (n=60)**	**p value**
	Mean (SD)	Mean (SD)	
Baseline HbA1C	9.97 (2.43)	9.44(2.06)	0.25
3 month HbA1C	8.52(1.69)	8.71(1.70)	.48
6 month HbA1C	8.01(1.46)	8.72(1.71)	.10
	n (%)	n(%)	
Percent on target for HbA1C at Baseline	30 (16.7%)	60(23%)	<.05
Percent on target for HbA1C at 6 months	29(59%)	29(31%)	<.05
LDL on target at 6 months	26(65%)	52(50%)	0.198
Blood Pressure on target at 6 months	30(90%)	60(88.5%)	0.83
On Target on all ABC at 6 months	32%	14.80%	0.24

Table 2
Sample Size at Baseline, 3 months and 6 months for SMA and Control Group

Group	Baseline	3months	6 months
Intervention	n=30	n=24	n=26
Control	n=60	n=36	n=29

Figure 1
Percent of Participants with HBA1Cs at Goal: Comparing baseline and 6 months later for SMA and Control Participants

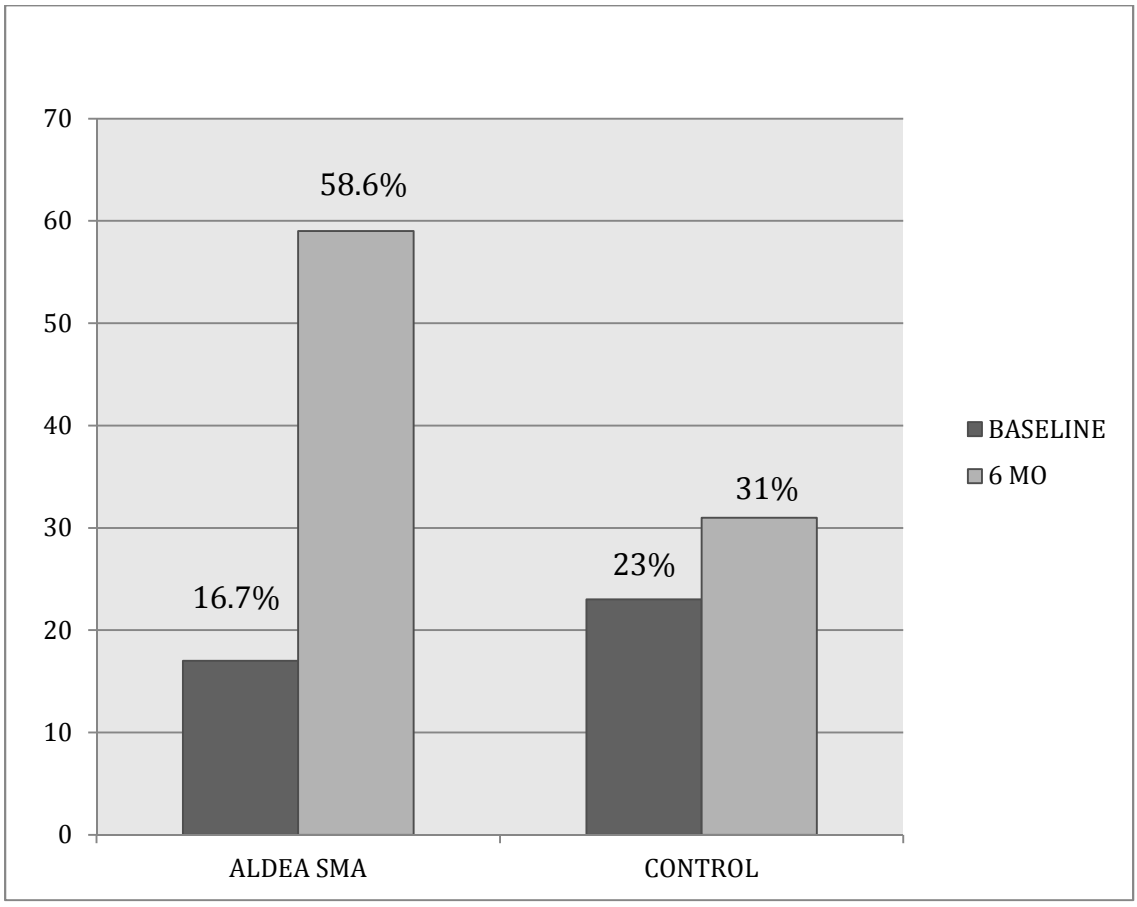


Figure 2

Mean HBA1C (%) at baseline, 3 months and 6 months for SMA and Control Participants

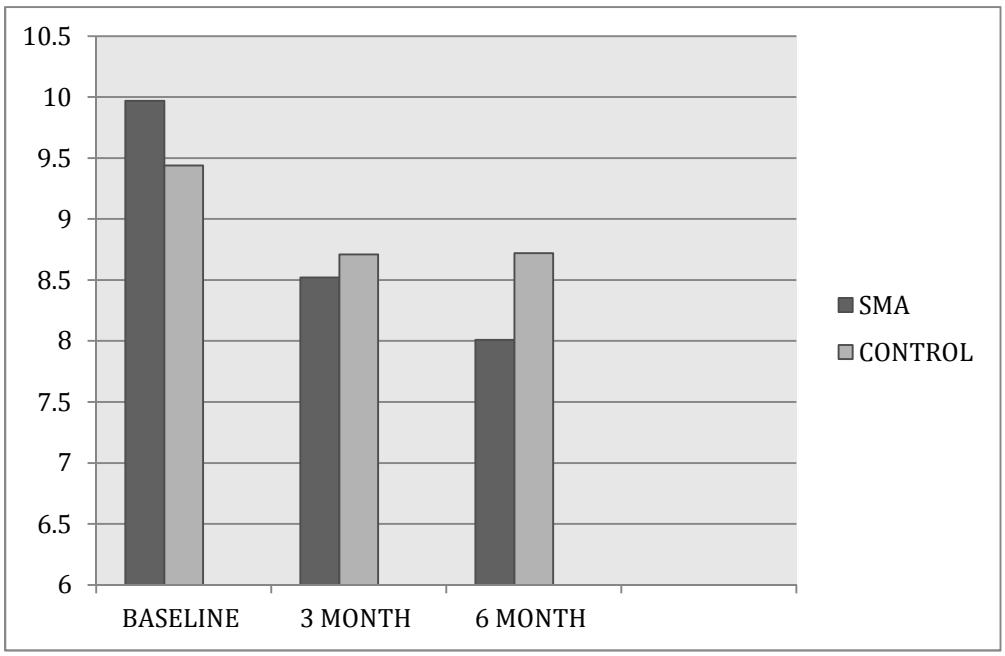
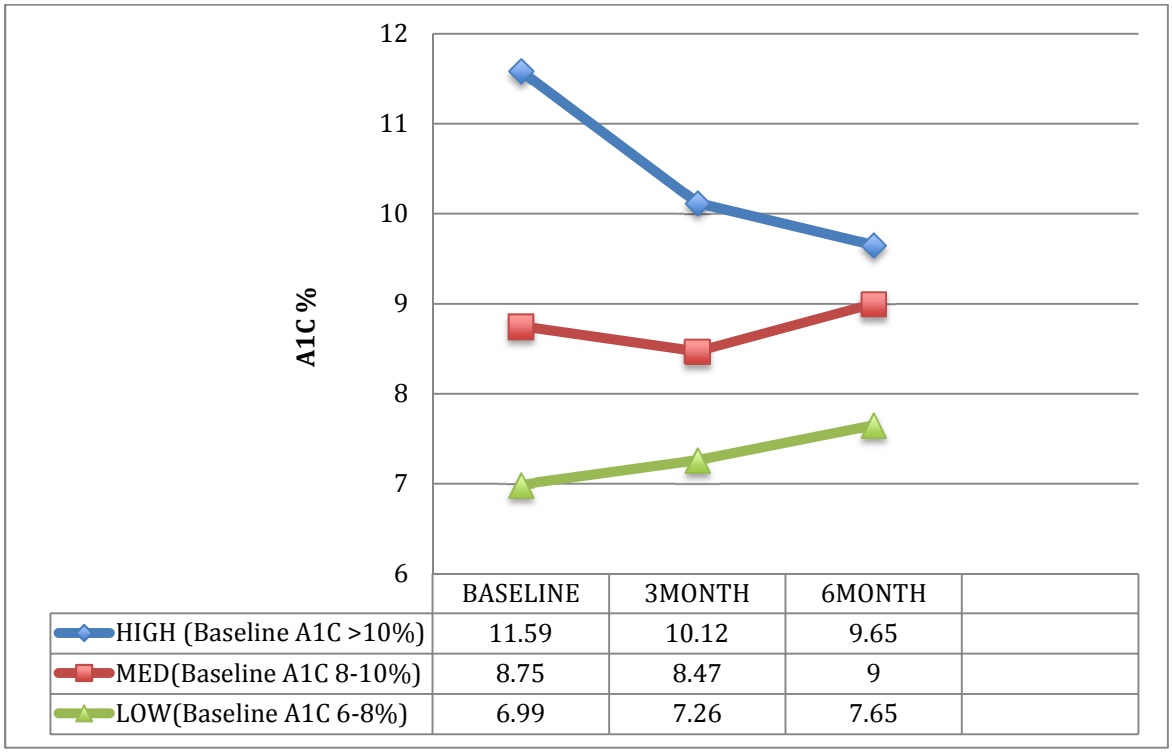


Figure 3

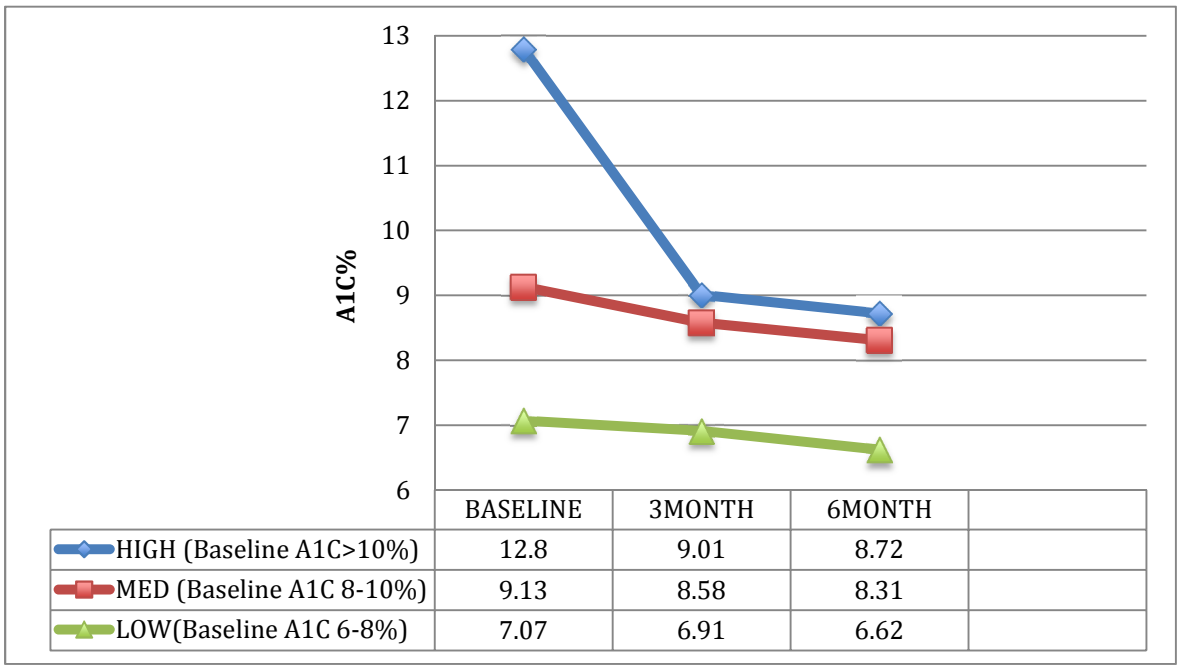
Mean HBA1C (%) at Baseline, 3 months and 6 months for Control Group, Stratified by Baseline HBA1C Values (High,Med and Low)



	BASELINE	3MONTH	6MONTH	
HIGH (Baseline A1C >10%)	11.59	10.12	9.65	
MED(Baseline A1C 8-10%)	8.75	8.47	9	
LOW(Baseline A1C 6-8%)	6.99	7.26	7.65	

Figure 4

Mean HBA1C (%) at Baseline, 3 months and 6 months for SMA Group, Stratified by Baseline HBA1C Values (High, Med and Low)



	BASELINE	3MONTH	6MONTH	
HIGH (Baseline A1C>10%)	12.8	9.01	8.72	
MED (Baseline A1C 8-10%)	9.13	8.58	8.31	
LOW(Baseline A1C 6-8%)	7.07	6.91	6.62	

Conclusion

The U.S. confronts a diabetes epidemic, with 1 out 11 people in the U.S. currently living with diabetes [1]. Moreover, type 2 diabetes, which accounts for 95% of the cases, affects ethnic minorities and those with low socio-economic status and low levels of education disproportionately [1]. The literature on the effectiveness of DSMES in improving HBA1C and blood pressure outcomes is clear [2]. Unfortunately, the effect of DSMES is lost over time unless the contact and support continues [3]. Moreover, despite the American Diabetes Association recommendation to include Diabetes Self-Management Education and Support as a core part of treatment for people with diabetes, only 48% of people with diabetes report attending DSMES [4]. In addition, less than half of people living with diabetes are at goal for their HBA1C (48%), 51% for low-density lipoprotein (LDL) and 72% for blood pressure. Less than 19% of the population with diabetes is at goal for all three metabolic markers.

Thus, there has been an urgency to incorporate DSMES into primary care and to redesign a system that has historically been reactive and designed for acute care, rather than proactive and designed for chronic disease management [5]. Shared Medical Appointments have been widely implemented in the VA system and more slowly in health maintenance organizations and community settings. Despite the research having limited generalizability, due to the exclusion of the uninsured and non-English speakers, there is evidence that SMAs have a positive impact on HBA1C and blood pressure, as well as quality of life and health care utilization to justify its implementation [6].

This dissertation aimed to develop, implement and evaluate the effectiveness of a shared medical appointment program (SMA), named ALDEA (Latinos con Diabetes en Acción), in an effort to close the disparity in diabetes outcomes for low-income Spanish speaking Latinos

residing in Central California. The author, in collaboration with a community-based clinic was able to design and implement a culturally adapted SMA program. ALDEA has been in operation since January 2015 and has grown to now offer two weekly groups. The process of cultural adaptation throughout the SMA program was transformative and resulted in a program that was patient centered and culturally tailored. Perhaps the most important aspect of this process was the level of engagement of participants.

The ALDEA SMA program enrolled 30 participants and had 60 matched control participants. It is important to note that the sample was highly impoverished and had a high number of uninsured participants (approximately 55%). Given their SES and insurance status, it it reasonable to assume that most participants experienced barriers to diabetes care, not least of which was the unavailability of a Spanish-language DSME program in the area. Despite barriers, 59% of the participants in the SMA program achieved goal HBA1C at 6 months, compared to only 31% of those in the control group. Moreover, 32% of SMA participants achieved their goal on all three measures, HBA1C, LDL and blood pressure, compared to 14.8% of the control participants, and compared with evidence that only 19% of patients with type 2 diabetes nationally achieve this goal. Additionally, the net reduction difference in HBA1C was -1.09% at 3 months and -1.23% at six months in favor of the ALDEA SMA program. In other words, at 3 months the SMA group had a reduction of -1.09% beyond that of the control group, and -1.23% at six months beyond the control group. This finding has real and important clinical implications. The United Kingdom Prospective Diabetes study helps contextualize these numbers. They found that for every 1% drop in HBA1C there is a 14% decrease in macro-vascular diseases, a 37% decrease in micro-vascular complications and a 21% decreased risk of

deaths related to diabetes [7]. Thus, improvements in HbA1C in the ALDEA participants likely have important long-term effects in patient's health outcomes.

It is acknowledged that this study has many limitations, including the lack of randomization, limited generalizability, and threats to internal validity due to possible study contamination. Nonetheless, the present study is among the first to provide initial evidence of the effectiveness of SMA for Spanish speaking Latinos, a group which has been excluded from most research in the past. Furthermore, the study suggests that offering and implementing SMA in a community based clinic, with family nurse practitioner students and volunteers, is a feasible and effective approach to delivering quality care for Latinos with diabetes. Future research should aim to determine the efficacy of SMAs as an inter-professional training venue. In other words, it may be possible to sustain and improve on this model by incorporating residents and students from pharmacy, medicine, nutrition and social work. The potential to provide a comprehensive and effective program to uninsured patients, while simultaneously providing students the opportunity to learn and train inter-professionally to deliver comprehensive diabetes care, is highly achievable.

This study provides initial evidence for the efficacy and acceptability of a culturally adapted SMA diabetes program for monolingual Spanish speaking Latinos. It is important that future research aims to measure processes of care delivery and psychosocial as well as physiologic indicators of change. Next steps in testing this intervention model would be to design a prospective, randomized trial to test program effectiveness with a more rigorous design. If such tests, prove positive, implementation trials across a variety of settings, would be warranted. Larger scale implementation trials would allow for the examination of mediators of change and identification of essential program elements.

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Appendices

Appendix D

University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Expedited Review Approval

Principal Investigator
Catherine Chesla, RN, PhD, FAAN

Type of Submission: Submission Correction for Initial Review Submission Packet
Study Title: Shared Medical Appointments: An Innovative Approach to Decrease Health Disparitites in Diabetes Outcomes Among Latinos living with type 2 Diabetes.

IRB #: 14-13782
Reference #: 159403

Committee of Record: Laurel Heights Panel

Study Risk Assignment: Minimal

Approval Date: 03/26/2016 **Expiration Date:** 03/25/2017

Regulatory Determinations Pertaining to this Approval:

Individual Research HIPAA Authorization is required for one or more subject groups. Use the Permission to Use
Personal Health Information for Research form.

The requirement for individual Research HIPAA Authorization is waived for some subjects, as detailed in the application. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:

(1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law;
(3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for

other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
(4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

A waiver of HIPAA Authorization and consent is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements:
(1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law;
(3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;

(4) the research could not practicably be conducted without the waiver; and (5) the study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

A waiver or alteration of informed consent is acceptable because, as detailed in the application: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.
The waiver or alteration of informed consent applies to some subjects, as detailed in the application.

This submission was eligible for expedited review as:
Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

All changes to a study must receive UCSF IRB approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4,
21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB website has more information.

Publishing Agreement

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Carolina Espinosa Noya

5/23/2017