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

Carolina Espinosa Noya, PhD,University of California, San Francisco
Catherine Chesla, PhD. University of California, San Francisco
Catherine Waters, PhD. University of California, San Francisco
Abbey Alkon, PhD. University of California, San Francisco

Carolina E.Noya PhD.
University of California, San Francisco
2 Koret Way, San Francisco, CA 94143
831-331-3751 (cell)
415-753-2161(Fax)
Carolina.Noya@ucsf.edu
Word Count 3,949
Tables #2
Figure #1

Abstract
The present study evaluated the effectiveness of a nurse practitioner led Shared Medical Appointment (SMA) intervention, compared to usual primary care (UPC) for the treatment of Latinos with type 2 diabetes and associated cardiovascular risk factors over a 6-month period. This study was a quasi-experimental design with a non-randomized matched control group that followed participants prospectively for 6 months. At baseline, blood glycemic profiles were not statistically different between the intervention and control group. The reductions in A1C 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). Compared to the control group, results of the linear regression analysis revealed a net reduction A1C difference of -1.09% from baseline to 3 months (p≤0.05) and -1.23% from baseline to 6 months (p≤0.01) in the intervention group.
This study demonstrated that the ALDEA SMA intervention led to a statistically significant net reduction of 1.09% at 3 months, and 1.23% at 6 months in A1C compared to UPC. Despite its limitations, the ALDEA SMA program has been successful in empowering Latino patients and improving glycemic control.

Introduction
        The prevalence of diabetes has increased exponentially over the last three decades and 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 prevalence rates among some ethnic minorities persist[1]. Additionally, disparities in the quality of care for adults diagnosed with type 2 diabetes have been documented, with fewer Latinos, African Americans and Native Americans receiving standard diabetes care, such as immunizations, foot examinations, ophthalmology screenings, and diabetes education, compared to their White counterparts [2].
        Although there has been steady improvement over the last 10 years in achieving recommended glycated hemoglobin (A1C), blood pressure (BP) and low density lipoprotein

(LDL) cholesterol goals, there continues to be a large percentage of patients, between 33%-49% who continue to miss target goals [3]. Nationally, only 14% of people with diabetes meet all three target goals (A1C, BP, and LDL), and are non-smokers [3]. Despite the known efficacy of Diabetes Self Management Education and Support (DSMES) [2], only half of adults with diabetes reported ever receiving formal diabetes education or attending self-management classes [3].

In response to these gaps in standard medical care for adults with diabetes, the American Diabetes Association (ADA) (2013) called for a change in the delivery of care to improve diabetes management and outcomes. Furthermore, the ADA proposed the Chronic Care Model (CCM) as an effective framework for improving quality of care for people with diabetes [4]. The CCM includes six core elements:1) delivery system redesign, 2) self-management support, 3) decision support, 4) clinical information systems, 5) community resources and policies and 6) health systems. Over the last decade evidence has emerged for the CCM as an effective framework to improve the care of individuals with chronic disease[5].

Shared Medical Appointments (SMA) is an intervention for adults with diabetes that includes at least three of the six core components of the CCM, delivery system redesign, self-management support, and decision support. SMA constitutes a model of care where planned visits are coordinated for a group of patients in the context of a multidisciplinary team [5, 6]. Over the last 15 years SMA has become an increasingly popular model of delivering 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 [7-11]. SMAs are a promising alternative to individual office visits because DSMES and peer support are integrated within the primary care visit, collaborative relationships between providers and patients can be nurtured, and group activities can be used to refine patients' disease management skills and enhance knowledge [12].

Research on the effectiveness of SMAs to improve diabetes outcomes for Whites has emerged, and there is sufficient evidence on the effectiveness of SMAs on A1C and BP to support the implementation of SMAs among White adults with type 2 diabetes [7, 12]. The impact of SMAs on A1C and BP is not only statistically significant, but also, more importantly, clinically significant. A meta-analysis revealed that SMAs improved A1C by 0.6 percentage points, findings similar to another meta-analysis [7]. While a change of 0.6% may seem modest, based on the United Kingdom Prospective Diabetes Study (UKPDS) findings [13], a decrease of 0.6% A1C 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 clinically significant change of 5 mm/Hg in systolic blood pressure among SMA participants [12]. 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 approximately 6.6 mm/Hg [14]. Edelman points out that SMA patients achieved 75% of the level of improvement seen with a first line medication for hypertension [12].

Unfortunately, the current literature on SMA effectiveness has, for the most part, excluded monolingual Spanish speaking Latinos (MSL) [15]. The only study to focus on low income uninsured Latinos was conducted by Guitierrez and colleagues in a randomized control trial (RCT) of 93 patients [#]. Unfortunately, the authors did not state if the participants were monolingual or bilingual or if the SMA was culturally tailored. Findings revealed a mean A1C decrease of 1.19% in SMA group (p<.01), versus a decrease of 0.67% for the control group

(p<0.02). There is a need to include Latinos in research and to expand the interventions to be culturally tailored for Spanish speaking Latinos living with type 2 diabetes.

Purpose of Study

The purpose of our study was to evaluate the effectiveness of a nurse practitioner-led behavioral SMA intervention, referred to as ALDEA (Latinos con Diabetes en Acción), compared to usual primary care (UPC) for the treatment of persons with type 2 diabetes over a 6-month period in a Federally Qualified Community Health Center (FQHC). The cardiovascular risks measured were A1C, LDL and systolic and diastolic BP. The primary outcome was A1C. Secondary outcomes were LDL and BP. The study of the ALDEA SMA model, as an innovative model of care for monolingual Latinos, has the potential to identify a sustainable and evidence-based, culturally tailored model of care to reduce health disparities.

Methods

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

Setting and Sampling

The recruitment of participants took place in a single FQHC in the California central coast serving low income people. Inclusion criteria were Spanish-speaking Latinos, >18 years of age with type 2 diabetes. Participants were referred by their primary care providers, recruited via flyers and phone calls using the diabetes registry at the FQHC. The non-probability convenience sample consisted of 90 participants receiving primary care at a FQHC clinic. The intervention (n = xx) and control group (n = xx) had a ratio of 1:2 participants.

The 30 participants who comprised the SMA intervention group were enrolled in 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. A total of 55 eligible participants were approached to participate in the ALDEA SMA program and 40 chose to participate, for a 72% participation rate. Lack of childcare was the primary reason for non-participation (70%). Of the 40 persons who chose to participate, 10 were excluded from the analysis because they attended less than three SMAs, leaving an intervention group of 30.

The control group was a non-random, matched sample who met the aforementioned inclusion criteria and received usual primary care (UPC) at the FQHC clinic. Intervention and control group participants were individually matched by age (within 5-10 years) and A1C levels (within 0.5-1%). Each SMA participant was matched with their controls within the same timeframe of the intervention so that baseline and follow-up data were consistent over time.

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 A1C at 6 months between the intervention and control groups. To achieve this mean change difference (medium effect) at p ≤ 0.05, two-tailed, the a priori sample size calculation indicated a total minimum sample of 84.

ALDEA Shared Medical Appointments Intervention

ALDEA is a culturally tailored SMA program, developed and implemented by the first author in the Spanish language at a single FQHC site [16][1]. The structure of the SMA

---

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

intervention was based on the model refined by the Veterans Affairs Office [10]. 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, where participants could join at any given time, and groups were limited to 12 patients per group. The SMA 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. There were a total of approximately 24 SMA sessions during the first 6 months of the program for each cohort.

The SMA sessions used a group process to provide support, education and patient activation. Motivational interviewing (MI) [17] 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. SMA visits included a brief individual medical evaluation during which 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. Additionally, medical care was coordinated with primary care services delivered by a different PCP within the FQHC.

Usual Primary Care

The UPC group participants received the clinic's standard of care for persons with diabetes. Standard of care consists of quarterly individual clinic visits with a primary care provider (i.e., MD, FNP or PA) of approximately 20 minutes. Referrals to DSMES in the community 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 A1C, systolic and diastolic BP and LDL at baseline and 6 months post baseline.

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 A1C. The primary outcome, A1C, 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 A1C levels collected during the interval was used. Hemoglobin A1C 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 A1C are part of the ADA guidelines of care for people with diabetes and were routinely collected in this clinic.

Low-density lipoprotein. The value of the last LDL, closest to the 6-month post-intervention data collection point, was utilized. Per current guidelines, the LDL variable was dichotomized (yes/no) as to whether the participant achieved the recommendation of <100 mg/dL [18]

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 clinic or SMA visit. Blood pressure values closest to the 6-month time post-baseline data collection point was used for analysis. Per current guidelines, the BP variable was dichotomized (yes/no) as whether the participant achieved the recommendation of <140/80 [18].

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, chi-square or Fisher exact tests. A1C was compared by group, at baseline and 3 and 6 months. Differences in the percentage of participants in each group who achieved A1C, LDL, BP and all three target goals, per the ADA guidelines, were compared at 6 months [4]. Lastly, to evaluate the impact of the subjects who left the study, differences in baseline demographics and A1C was compared between participants with complete versus missing data.

To test the effect of group membership on A1C change, differences in change scores were compared between the ALDEA SMA intervention group and the UPC. Linear regression analysis was computed to assess if mean A1C change from baseline to 3 and 6 months was greater among SMA intervention group participants compared to the UPC control group participants.

Results

There were a total of 24 SMA sessions during the first 6 months of the program for both intervention cohorts. Each session included a mean of 7 participants, who attended a mean of 13 SMA sessions.

The mean age of the sample was 53 years ±12.3. All of the participants were at or below the Federal Poverty Line at 100%. In the sample, 61% had health insurance and participants had an average of 2.4 ±1.4 chronic conditions per medical records (Table 1). There were no significant differences at baseline between ALDEA SMA intervention cohorts 1 and 2 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 cohorts 1 and 2 were combined for the remaining of the analyses. There were no statistically significant differences on demographic variables or baseline A1C between those with complete or missing data.

Demographics: At baseline, 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) between the ALDEA SMA intervention group and the matched UPC control group.

A1C: There was a statistically significant difference (χ^2= 4.462, p≤ 0.05) in the percentage of participants that achieved the target A1C goal at 6 months post-intervention for the SMA participants (58.6%) versus the control group participants (31%) (Figure 1). The reductions in A1C were greater in the intervention group relative to the control group at both 3 months (-1.69% vs. -0.59%, t=-2.156, p≤0.05) and 6 months (-1.48% vs. -.241%, t=-2.458, p≤0.05) (Figure 2). Compared to the control group, there was a net reduction A1C difference of -1.09% (b= -1.09, p<.05, R^2 =0.77, F(df)=4.65(1/56), p<0.04) from baseline to 3 months and a net reduction of -1.23% (b = -1.23, p<.016, R^2 =.11, F(df)=6.17(1/51), p<.016) from baseline to 6 months with more positive results for the SMA group.

Blood Pressure and LDL: The majority of the participants in the intervention group (90%) and in the control group (89%) had on-target BP values at 6 months (χ^2=.045, p=.832). Sixty-five percent of SMA participants compared to 50% of control group participants had on-target LDL values at 6 months (χ^2=1.66, p=.198) (Table 2). Lastly, although not statistically significant it is of clinical significance to note that 32% of intervention group participants compared to 15% of control group participants achieved the on-target goals for all three criteria (A1C, LDL and BP) (χ^2=2.83, p=.24) (Table 1).

Discussion

To our knowledge, this quasi-experimental study with a matched control group is among the first to document the impact of a culturally-adapted SMA model to improve glycemic control among low-income, Spanish-speaking Latinos living with type 2 diabetes. This study demonstrated that underserved Latinos enrolled in the ALDEA program, a culturally sensitive, community based, nurse practitioner-led, SMA model, was able to achieve A1C 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 A1C over the 6-month period compared to UPC participants. These differences are also clinically significant and are larger than other studies of SMA effectiveness in reducing A1C. Edelman and colleagues reported in their meta-analysis a net reduction of 0.6% in A1C in favor of SMA [15]. In terms of clinical significance, the United Kingdom Prospective Diabetes Study found that a 1% decrease in A1C 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 [13].

The prevalence of adults with type 2 diabetes that meet the A1C, BP and LDL recommendations in the U.S. vary by ethnicity [3]. Stark and colleagues analyzed NHANES data and noted that Mexican Americans were less likely than their White counterparts to meet A1C and LDL goals, 52% vs. 46% and 62% vs. 45% respectively [3]. The ALDEA SMA participants demonstrated a higher percentage of achieving recommended goals compared to the UPC participants for A1C (58.6% vs. 31%), BP (90% vs. 85%) and LDL (65.4% vs. 50%) and 32% of the ALDEA SMA group vs. 15% of the UPC group met all three criteria. Thus, ALDEA SMA participants achieved overall goals well above national trends both for Latinos and for the NHANES sample, suggesting the importance and relevance of culturally-tailoring an intervention, such as ALDEA SMA, that is population and linguistically specific.

Although these are novel findings, there were 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 already been 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. The treatment and control groups were from the same clinic and the medical providers may have influenced each other in some way. For example, implementation of the ALDEA SMA program might have influenced primary care providers and influenced them to inadvertently change the medical care of control participants. This bias could have underestimated the outcomes found in the study.

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. Future studies should asses the feasibility and efficacy of the ALDEA SMA intervention in different settings, with different populations, degree of generation and acculturation, and with a different team composition.

Future research on the effectiveness of SMA as a model of care for Latinos should attempt to close some of the 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, that is, dose, 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 by ethnic group, setting and gender.

It is important to note that unlike other SMA teams described in the literature which often included multiple licensed professionals (i.e. pharmacist, medical doctors, psychologists), this team was small and included a nurse practitioner, nurse practitioner students, a volunteer nurse and a medical assistant. The cost analysis of this team approach is important as it may be a cost-effective approach to reach the most vulnerable and low resourced populations.

In conclusion, given the disproportionate rates of type 2 diabetes and poor outcomes among Latinos in the US [1], it is important that research studies include this vulnerable population. 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, underserved Spanish speaking Latinos lead by a nurse practitioner that showed a significant decrease in A1C at 6 months post-intervention.

Despite its limitations, the ALDEA SMA program has been successful in engaging Latino patients and improving glycemic control; its innovation could be diffused and tested in other settings, populations and health conditions. The ALDEA SMA model has the potential to reach underserved communities and result in significant improvements in the health status among the most vulnerable populations.

Acknowledgements

C.N researched data and wrote the manuscript. The remaining three authors reviewed and edited the manuscript.

The authors have no conflict of interest to report.

Dr. Carolina Noya is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

References
1.	Prevention, C.f.D.C.a., *Estimates of Diabetes and Its Burden in the United States*. 2014, U.S. Department of Health and Human Services: Atlanta, GA.
2.	Brown, S.A. and C.L. Hanis, *Lessons Learned from 20 Years of Diabetes Self-Management Research With Mexican Americans in Starr County, Texas*. Diabetes Educ, 2014. **40**(4): p. 476-487.
3.	Stark Casagrande, S., et al., *The prevalence of meeting A1C, blood pressure, and LDL goals among people with diabetes, 1988-2010*. Diabetes Care, 2013. **36**(8): p. 2271-9.
4.	*Standards of Medical Care in Diabetes-2017 Abridged for Primary Care Providers*. Clin Diabetes, 2017. **35**(1): p. 5-26.
5.	Coleman, K., et al., *Evidence on the Chronic Care Model in the new millennium*. Health Aff (Millwood), 2009. **28**(1): p. 75-85.
6.	Wagner, E.H., et al., *Improving chronic illness care: translating evidence into action*. Health Aff (Millwood), 2001. **20**(6): p. 64-78.
7.	Housden, L., S.T. Wong, and M. Dawes, *Effectiveness of group medical visits for improving diabetes care: a systematic review and meta-analysis*. CMAJ, 2013. **185**(13): p. E635-44.
8.	Edelman, D., et al., *Medical clinics versus usual care for patients with both diabetes and hypertension: a randomized trial*. Ann Intern Med, 2010. **152**(11): p. 689-96.
9.	Cohen, L.B., et al., *Pharmacist-led shared medical appointments for multiple cardiovascular risk reduction in patients with type 2 diabetes*. Diabetes Educ, 2011. **37**(6): p. 801-12.
10.	Taveira, T.H., et al., *Pharmacist-led group medical appointments for the management of type 2 diabetes with comorbid depression in older adults*. Ann Pharmacother, 2011. **45**(11): p. 1346-55.
11.	Taveira, T.H., et al., *Pharmacist-led group medical appointment model in type 2 diabetes*. Diabetes Educ, 2010. **36**(1): p. 109-17.
12.	Edelman, D., et al., *Shared Medical Appointments for Patients with Diabetes Mellitus: A Systematic Review*. J Gen Intern Med, 2014.
13.	*Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group*. Lancet, 1998. **352**(9131): p. 837-53.
14.	Piller, L.B., et al., *Characteristics and Long-Term Follow-Up of Participants with Peripheral Arterial Disease During ALLHAT*. J Gen Intern Med, 2014.
15.	Gutierrez, N., et al., *Shared medical appointments in a residency clinic: an exploratory study among Hispanics with diabetes*. Am J Manag Care, 2011. **17**(6 Spec No.): p. e212-4.

16. Castro, F.G., M. Barrera, Jr., and L.K. Holleran Steiker, *Issues and challenges in the design of culturally adapted evidence-based interventions.* Annu Rev Clin Psychol, 2010. **6**: p. 213-39.

17. Rollnick, W.R.M.a.S., *Motivational Interviewing: Helping People Change*. 2012, New York: Guilford Press.

18. Cornell, S., *Comparison of the diabetes guidelines from the ADA/EASD and the AACE/ACE.* J Am Pharm Assoc (2003), 2017.