Community-based Lifestyle Intervention for Underserved Hispanics with

Pre-diabetes and Type 2 Diabetes in Southwest Virginia

Ivette Guadalupe Valenzuela

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Kathryn Hosig, Chair

Elena Serrano

Kerry Redican

Carlos Evia

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Abstract

In the U.S., diabetes mellitus cases have been increasing, from 25 million in 2010 to 29 million in 2012. Healthy People 2020, the U.S. National Health Agenda, has established specific goals and objectives for diabetes. In the U.S., prevalence of pre-diabetes and diabetes for adult Hispanics was 38% and 12%, respectively, in 2012. The total estimated diabetes cost in the U.S. has been increasing, from $176 billion in 2007 to $245 billion in 2012.

The current study had two research hypotheses; the formative phase was expected to demonstrate a need for a community-based Type 2 Diabetes Mellitus (T2DM) self-management intervention for Spanish-speaking Hispanics. Random Control Trial (RTC) was expected to demonstrate the potential impact in preventing and managing T2DM.

Methods. A community-based lifestyle education curriculum was translated into Spanish, and adapted to Hispanic culture. This study includes three phases: 1) a formative phase; 2) a two-group pilot RCT with Hispanic Living with Diabetes (HBLD) and a delayed treatment condition; and 3) post-HBLD focus groups held with three participating groups of HBLD.

Results. Of 60 participants screened in the formative phase, 62% had A1c $> 5.7\%$, and 75% did not have medical insurance. Of 6 participants who completed the pilot, A1c decreased for all six participants. Of 67 participants screened in phase 2, 61% had A1c $> 5.7\%$. Of 30 HBLD participants in the RCT, baseline versus 3-month mean A1c increased 0.2 for the delayed control group (n = 10) and did not experience any change for the intervention group (n = 11). The difference in A1c change from baseline to follow up between treatment groups was not statistically significant (Kruskal Wallis, $p < 0.05$). Diabetes knowledge and SCT variables

change from baseline to follow-up between groups were not statistically significant. Major themes identified in focus group discussions included barriers to access to health and nutrition services, the value of having a Spanish-speaking Hispanic as a health educator, and barriers to recruiting community members as *promotoras*.

Implications. HBLD has potential to reduce complications of diabetes among Hispanic participants by providing education to those who may not otherwise have access to it.

Dedication

This *dissertation is dedicated to my daughter Alexia Granados. She has been my inspiration and my motivation to improve myself every day.*

To my parents, Isidro A. Valenzuela and Elsy de Valenzuela for having sacrificed everything so that I could strive for my dreams.

To my husband Steve Yu thank you for loving us and taking care of us. You fill my heart with joy.

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Attribution

The committee chair, Dr. Hosig, is included as co-author; she provided guidance in research design and implementation. Dr. Evia, Dr. Serrano, and Dr. Redican were included as co-authors in Chapter 3; they contributed in the writing and provided guidance as needed for research design during the committee meetings. Dr. Schlenker was also included for her guidance in implementing the intervention and for her support during the research assessments.

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CHAPTER 1

Introduction

Diabetes Mellitus

Diabetes Mellitus (DM) is a chronic disease that is developed when the pancreas does not produce insulin or when it does, but the body is not able to use it.[1] DM is classified as gestational diabetes, type 1 Diabetes Mellitus (T1DM), and type 2 Diabetes Mellitus(T2DM). T2DM causation has a genetic and lifestyle component[1], and accounts for 90% and 95 % of diabetes cases in the world (2014) and in the U.S. (2012) respectively.[1, 2]

Diabetes Mellitus and pre-diabetes prevalence

In 2014, the worldwide prevalence of DM for those 18 years old and older was 9.0%.[1] The total U.S. prevalence of DM in 2012 was 9.3 %; one in four did not know they had high blood sugar.[2] The prevalence of diabetes in 2012 was higher for Hispanics (12.8%) than for non-Hispanic whites (7.6%).[3] About 37% of U.S. adults had pre-diabetes in 2013; 90% of these did not know that they had it. Pre-diabetes prevalence in Hispanics (38%) was also higher than for non-Hispanic whites (35%) in 2012.[3] In Virginia, the prevalence of DM and pre-diabetes was about 11% and 25% respectively.[4] Health disparities and social determinants of health are prompting lifestyles that increase T2DM incidence in racial and ethnic minorities.[5]

Economic Costs of DM

In 2012, the total estimated cost of DM and pre-diabetes was $322 billion (Pre-diabetes, $44 billion, undiagnosed diabetes, $33 billion, and diabetes, $245 billion).[6] Economic costs associated with DM have been steadily increasing; the total cost of diabetes was $132 billion in 2002, and $174 billion in 2007. [4,7-9] In 2012, DM costs accounted about 23% of total U.S. healthcare expenditures.[7] Out of the $245 billion in diabetes costs, direct medical costs were

$176 billion and $69 billion were indirect.[7] The largest direct medical costs were attributed to hospital inpatient care (43%) and treatment of DM complications (18%).[7] The largest indirect costs were related to inability to work due to disability (31%) and decreased productivity while at work (30%).[7] Costs of diabetes care were paid mainly by the government (62.4%), followed by private insurance (34.4%), and out of pocket costs paid by the uninsured (3.2%).[10] The total cost of diabetes is projected to increase to $514 billion by 2025.[4] In Virginia, the total diabetes costs for Hispanic Americans in 2010 was $515 million and is projected to increase to $1.2 billion by 2025.[4]

Healthy People 2020 and diabetes

Healthy People 2020 is a U.S. national public health agenda with a mission to improve health and achieve health equity. Objectives for specific topic areas are set and measured over a decade. Healthy People 2020 has created national diabetes goals and objectives to decrease the burden of diabetes on Americans. These objectives include:

- (D-11) Increase the proportion of adults with diabetes who have a glycosylated hemoglobin measurement at least twice a year;

- (D-14) Increase the proportion of persons with diagnosed diabetes who receive formal diabetes education;

- (D-15) Increase the proportion of persons with diabetes whose condition has been diagnosed; and

- (D-16) Increase prevention behaviors in persons at high risk for diabetes with pre-diabetes.[11]

Research hypothesis

Participation by underserved Hispanic adults with pre-diabetes or type 2 diabetes in a lifestyle educational intervention grounded in Social Cognitive Theory (SCT) and Community-based Participatory Research (CBPR) will improve glycemic control (A1c), serum lipids, and SCT variables (self-efficacy, self-regulation, and social support) compared with participants in a delayed treatment group.

Primary Aims

1. Deliver and collect formative data for a community-based diabetes lifestyle intervention tailored for Hispanic adults with pre-diabetes or type 2 diabetes;

2. Increase awareness of pre-diabetes and type 2 diabetes risk among the Hispanic population;

3. Provide preliminary data for outcomes of A1c and serum lipids three months after implementation of HBLD compared to a delayed treatment control; and

4. Explore the feasibility of creating a partnership between Cooperative Extension and Catholic churches to reach underserved Hispanics with health programs.

Secondary Aims

1. Evaluate the need for diabetes education among Hispanics;

2. Collect data regarding social determinants of health for Hispanics; and

3. Assess the feasibility of finding community members to volunteer to receive training as *promotoras/*patient navigators.

Theoretical Framework

Hispanic Balanced Living with Diabetes (HBLD) is an educational, mixed methods study grounded in SCT and CBPR. SCT is an interpersonal health behavior theory that explains the

dynamic interaction and influence among personal and environmental factors and human behavior.[12] Constructs included in SCT are environment, reciprocal determinism, behavioral capability, outcome expectations, self-efficacy, self-regulation, observational learning, and reinforcement.[12,13] HBLD was adapted from Balanced Living with Diabetes (BLD), which was adapted for the Virginia Cooperative Extension (VCE) from Dining with Diabetes (DwD), which was originally developed by the West Virginia Cooperative Extension.[14] HBLD is designed to address SCT constructs including outcome expectations, self-efficacy, self-regulation, reinforcement and social support, and observational learning. CBPR is a collaborative approach and takes into consideration the expertise and contribution of stakeholders such as community leaders, researchers, and other stakeholders.[15] CBPR has been used successfully when implementing and adapting diabetes prevention programs to underserved Hispanic populations[16]; CBPR has also been used when developing partnerships with Catholic churches, Hispanic community members, and other institutions.[17] CBPR principles include:[18,19]

- Recognition of community as a unit of identity,

- Facilitation of collaborative partnerships in all phases of the research,

- Integration of knowledge and action for the mutual benefit of all partners,

- Promotion of a co-learning and empowering process that attends to social inequalities and addresses health from both positive and ecological perspectives, and

- Dissemination of findings and knowledge gained to all partners.

Significance

Hispanics became the largest minority (17%) in the U.S. in 2012[20] and are estimated to represent 31% of the U.S. population by 2060.[20] Total diabetes prevalence in the U.S. is

projected to increase to 14.5% by 2031; during the same period, diabetes prevalence in Hispanics is estimated to increase to 20% .[21]

In 2013, diabetes was the 7th leading cause of death in the U.S.; for Hispanics, diabetes was the 4th leading cause of death.[22] Also, in 2013, the diabetes mortality rate (28.3 per 100,000) among Hispanics was 53% higher when compared to non-Hispanic whites (18.7 per 100,000).[19] Hispanics have a higher risk of having diabetes or pre-diabetes.[5, 22] Lack of or low healthcare access is one of the barriers faced by this group.[22] Diabetes prevalence in Hispanics has been negatively associated with low educational level and income.[23] Therefore, developing and implementing culturally and linguistically appropriate programs is crucial in order to decrease health disparities and increase equity among Hispanics.

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CHAPTER 2

Background and Literature Review

Social determinants of health

About 80% of people in the world with a diagnosis of diabetes live in low- or middle-income countries.[1] According to the World Health Organization (WHO), social determinants of health are the conditions in which people are born, live, grow, work, and age.[2] Social determinants of health are shaped by financial resources, distribution of power, and allocation of resources at the personal, community, state, national, and global levels[3]. Social determinants of health might influence, in a positive or negative way, the health outcomes of a population and quality of life.[4,5] Social determinants of health include access to healthcare services, availability of community-based resources, social support, social norms and attitudes, socioeconomic conditions, residential segregation, language/literacy, and culture.[5]

Understanding the negative impact of social determinants of health on Hispanic health outcomes

In the U.S., social determinants of health that negatively affect the health outcomes of Hispanics include, but are not limited to: access to healthcare, limited English proficiency, low educational attainment, and poverty levels.[6-9]

Health care access. Access to health care in Hispanics varies depending upon health insurance and immigration status, cost concerns, and language.[8, 10-14]

Health insurance and immigration status. Lack of inadequate health insurance leads to lack of access to healthcare and preventive healthcare services.[10] In 2013, 42% of Hispanics lacked health insurance.[8] The Patient Protection and Affordable Care Act (ACA) does not include

coverage for non-citizens and undocumented immigrants.[7] In 2012, 43% of uninsured Hispanics were non-citizens.[12] Inequalities resulting from discrimination on the basis of race, gender, and immigration status reduce access to federally funded services to some U.S. residents; undocumented residents do not qualify for federally funded services and legal residents do not qualify during their first five years of residence in the U.S.[15] In 2014, Hispanics represented 8.9% of the population of the Commonwealth of Virginia.[16] The majority of Hispanics are located in Northern Virginia.[16] In 2014, Hispanics represented 22.4% of the population in Prince Williams County, 33.4% in Manassas Park City, and 34% in Manassas City.[16] In 2011, 55 % of foreign born Hispanic children did not have health insurance in Virginia.[17]

Being uninsured with diabetes. In 2012, uninsured patients with diabetes had 79% fewer physician visits and 68% fewer prescriptions for medication than those with insurance. The impact of fewer physician visits and prescriptions resulted in a 55% increase in the number of emergency room visits compared with insured patients with diabetes.[18]

Health insurance costs. In 2013, 15.5% of Hispanics did not receive or had delayed medical services due to the prohibitive expenses of health related costs.[8] In 2012, 3.2 % of diabetes medical expenditures were paid out of pocket by uninsured patients.[18]

Limited English proficiency. An individual whose primary language is not English and who has limitations in reading, speaking, writing, or understanding English, is referred to as having Limited English Proficiency (LEP).[19] In 2012, about 38.3 million U.S. residents ≥ 5 years of age spoke Spanish at home; approximately 58% of those spoke English very well.[20] Limited English proficiency might act as healthcare barrier and create misunderstandings among providers and patients. [21-23] Ineffective communication can lead to negative health outcomes due to

misdiagnosis and poor patient compliance and may increase patient costs due to unnecessary testing. Therefore, patients might report poor satisfaction with these services.[23]

The importance of using Culturally and Linguistically Appropriate Services (CLAS) for LEP patients was established by Title VI of the Civil Rights Act in the Executive Order 13166 "Improving Access to Services for Persons with Limited English Proficiency." According to this Executive Order, it is an act of discrimination to deny or delay medical care due to language barriers.[24] The need for increased culturally and linguistically appropriate services is aggravated by the disproportionate ratio of Hispanics to Hispanic health professionals. In 2012, Hispanics comprised only 6% of U.S. physicians and 9% of graduates from public health schools. [25, 26]

Educational level. In 2013, there were about 53 million Hispanics living in the U.S. Of those, the median age was 28, about 35 % had less than a high school education, 74 % spoke a language other than English at home, 32 % spoke English less than "very well," 25 % lived below the poverty line, and 7% were unemployed.[8]

According to data from the 2010-2012 National Health Interview Survey[27], diabetes was more prevalent in participants with lower education levels. Adults with a bachelor's degree or higher accounted for 7% of diabetes cases, compared with 15% of adults with less than a high school diploma**.** Educational attainment may play a role in developing or preventing diabetes. Disparities in educational attainment are prominent in Hispanics (Table 1 and 2).

Table 1. Educational attainment for 25 years and older in U.S and Virginia.[28, 29]

Racial or Ethnic Group	U.S. 2013[28]		Virginia 2010[29]	
	High school degree or higher	Bachelor's degree or higher	High school degree or higher	Bachelor's degree or higher
Hispanics	66.8%	22.5%	66%	15%
Non-Hispanic Whites	89.2%	31.7%	92%	32%

Income. In 2012, the average salary for white males with a bachelor's degree was higher than for Hispanics with a bachelor's. Also in 2012, the average salary for white males with a master's degree was $56,900 compared with $50,000 for Hispanics with a master's degree.[30]

<div align="center">Diabetes burden in Hispanics</div>

In 2010, diabetes was the 5th leading cause of death in Hispanics.[31] In 2013, as diabetes prevalence increased; diabetes was the 4th leading cause of death for Hispanics and 7th leading cause of death in total U.S. population.[8] In 2013, the prevalence of diabetes was 14% amongst Hispanics (15.3% in Mexican Americans), which was higher when compared with non-Hispanic whites (6%).[8] The rate of being diagnosed with diabetes is higher for Hispanics of Mexican origin (87% higher) and Puerto Rico (94% higher) when compared with non-Hispanic whites.[32] Diabetes costs for Hispanics were estimated to be $50 billion in 2012; these costs are projected to increase to $100 billion by 2025.[33,34]

Reduction of diabetes complications through glycemic control and management of serum lipid levels

Glycemic control and management of serum lipid levels is crucial to delay and/or prevent diabetes complications. [35] Glycemic control was poor (>9.0%) in 12% of Americans between 2007-2010; poor glycemic control was higher amongst Hispanics, at 19%, compared with non-Hispanic whites at 10.1%.[38] According to the Standards of Medical Care in Diabetes, the A1c recommended goal in non-pregnant adults is <7%. Keeping A1c <7% has been proven to decrease microvascular complications associated with diabetes.[37] Long-term reduction of macrovascular complications in patients newly diagnosed with diabetes is also associated with maintenance of A1c below 7 % .[35-37] People with diabetes are at higher risk for cardiovascular disease (CVD).[39] Recommendations to reach serum lipid goals include lifestyle modification and

statin therapy.[35, 39] Statin therapy recommendations are based on age (<40 years, between 40-75 years, and > 75 years), overt CVD status (presence of previous cardiovascular events or acute coronary syndrome), and CVD risk factors (LDL cholesterol $\geq$ 100 mg/dL, high blood pressure, smoking, being overweight, and/or obesity). [35, 39] Serum LDL goal in individuals without overt CVD is 100 mg/dL; serum goal in individuals with overt CVD is 70 mg/dL.[35]

<div align="center">

Hispanic Culture

</div>

Familismo, [40, 41] collectivism, [42, 43] culture, religion, and *simpatía* are important in the Hispanic culture and should be incorporated in the implementation of interventions targeted toward Hispanics.[44-47]

Familismo

Familismo implies the importance of being connected and close to the family; family support is important in Hispanic lives.[40] Limitations in family knowledge about diabetes could serve as a barrier to diabetes support; family can be a contributing factor to developing diabetes when relationships between family members are not as good as expected.[41] *Familismo* calls to deliver health promotion and disease prevention interventions targeting the family as a whole.[42]

Collectivism

Having a collectivist value, that is, values oriented towards group goals above individual ones, highlights the basis for how individuals identify themselves as part of a group and how their goals correspond with group goals.[43] Hispanics in general have more collectivist values than non-Hispanic whites, and are more likely to work in a community environment.[44] Community interventions have shown improvement in diabetes self-management. [45-50]

Culture

Understanding cultural diversity is important when developing and implanting interventions with the Hispanic community**.** Beliefs associated with the disease process are important when delivering diabetes health promotion interventions; strong emotions have been linked with development of diabetes.[41] Cultural values are linked with society; therefore, the degree of acculturation needs to be addressed when considering the country of origin and religion of Hispanics.[45]

Simpatía

Simpatía means "kindness" and strongly suggests politeness and pleasantness even when the individual is surrounded by stressful situations. Avoiding confrontation is part of *simpatía*. Hispanics might be less able to express openly their opinion or disagreement with a treatment plan. [40]

Religion

Religion refers to an organized and centralized practice that has been established by tradition.[51] In 2007, about 59% of Virginia adults said that religion is important in their lives.[52] In 2012, 60% of Hispanics said that religion is important in their lives.[53] In 2002, about 70 % of Hispanics in the U.S. were Roman Catholic.[54, 55] In 2007, Hispanics represented 33% of U.S. Catholics.[56]

Culturally and linguistically tailored lifestyle intervention programs for diabetes

Translation of the Diabetes Prevention Program (DPP) from the clinical to community setting has shown improvement on anthropometric measurements, serum lipids, and changes in behaviors.[57-59] Strong social support has been associated with decreased prevalence of diabetes in Hispanics.[60] Faith-based diabetes interventions delivered to Hispanics have been shown to increase social support and improve lifestyle associated with diabetes.[61,62] Bilingual self-

management training has been proven to decrease A1c, LDL, and blood pressure and to increase self-efficacy and knowledge about physical activity and healthy eating in Hispanics.[48,63,64] Lifestyle interventions at community levels have also resulted in significant improvements in anthropometrics and behaviors.[50]

A prospective quasi-experimental study was conducted in the Texas counties of Hidalgo and Starr to evaluate the effectiveness of culturally appropriate diabetes self-management education (DSME).[64] The Hispanic community represented more than 85% of the population in both counties; diabetes prevalence was higher when compared to the U.S. as a whole. Hidalgo and Starr Counties were medically underserved areas, with high poverty rates and limited health care resources.[64] An educational intervention based on SCT and Self-Regulation theory was delivered in community settings (churches and libraries) by a bilingual registered nurse and dietitian. Total participants (n=144) including intervention and wait list controls were tested at baseline and three months after intervention. Inclusion criteria included self-identification as a Hispanic/Latino, being 40 and older, and having a T2D diagnosis.[64] When comparing baseline and three month assessment data, A1c decreased significantly for the intervention group with a median difference of 0.3; and the intervention group showed significant improvement in self-efficacy and self-care scores ($p=0.0$).[64]

In southwest Chicago, Illinois, a non-randomized prospective intervention study using a single group design evaluated the outcomes of translating a clinical-based diabetes prevention program into Spanish.[50] The educational intervention was culturally and linguistically adapted by using the principles of CBPR and was delivered by community health workers (CHWs). This study enrolled participants (n=69) during a health fair. Inclusion criteria were adults aged 18 to 65 years having glucose screening results between normal and pre-diabetes range, with a body

mass index (BMI)> 24.9, not pregnant, self-identifying as Latino, residents in the target community, and not having a medical condition that limited the dietary and physical activity required to carry out the program's goals. Anthropometric measurements (weight, BMI, and body fat) were assessed every month; 20% of the participants achieved a 7% weight loss goal at 6 months and 16% achieved a 7% weight loss goal at 12 months.[50]

In southeast Chicago, a non-experimental pretest-posttest single group evaluated the effectiveness of a culturally and linguistically appropriate educational intervention in Hispanics/Latinos with T2DM.[49] The educational intervention comprised 2-hour group sessions over 10 weeks, delivered in community settings by CHWs.[49] Inclusion criteria included age (18 or older), self-identification as Hispanic/Latino, residence in a Southeast Chicago community (and/or surrounding areas), and a diagnosis of diabetes.[49] A1c and blood pressure improved significantly ($p = .001$) and ($p = .006$) respectively from pre-test to post-test (n=47).[49]

In Lawrence, Massachusetts, a randomized control trial (n=289) evaluated the outcomes of a community-based, culturally, linguistically, and literacy sensitive lifestyle intervention.[65] This educational intervention was adapted from the DDP and was based on SCT with patient-centered counseling.[65] Three Spanish speaking members of the community were trained to deliver the intervention in participant homes and community settings.[65] The intervention consisted of three individual and thirteen group sessions over a year.[65] Inclusion criteria included self-reported Latino/Hispanic ethnicity, age >25 years, BMI > 24, and a risk of 30% or greater of being diagnosed with diabetes over the next 7.5 years.[65] The treatment group showed 2.5 lb of weight reduction versus the control group, with a gain of 0.63 lb ($p= 0.04$). A1c decreased by 0.10% for the treatment group and 0.04% for the control group ($p=0.009$).[65]

In South Lawndale, a neighborhood of Chicago, Illinois, a church-based randomized control trial (n=100) evaluated diabetes self-management outcomes among Latino adults.[61] The educational intervention was delivered by trained community leaders who were members of the church. Leaders were trained on program content based on the Transtheoretical Model, SCT, Self-Determination Theory, and principles of motivational interviewing. Following principles of CBPR, a partnership was developed with two Catholic churches, a Catholic social service agency, healthcare leaders, and community members.[61] Participants were assigned randomly to an intervention group (n=50) or to a 90-minute diabetes lecture (n=50).[61] The intervention group participated in eight weekly group classes. Participants in both groups were assessed at baseline and three months post-intervention. A1c decreased in both groups (−0.32 %, 95 % confidence interval [CI]: -0.62, -0.02 %).[61]

Implications

The reported outcomes of these programs demonstrate that culturally appropriate programs for Hispanics can be effective for diabetes self-management and have the potential to prevent progression of pre-diabetes to diabetes. To improve health outcomes for Hispanics, researchers and health professionals must be cognizant that Hispanics include individuals from different countries and that working effectively with Hispanics requires understanding of Hispanic cultural values. Developing and implementing interventions for Hispanic populations requires programs that are culturally and linguistically sensitive and appropriate. Most studies with Hispanic populations have taken place in Illinois, Texas, California, and Massachusetts.[48-50, 61,62, 64,65] In 2013, eight states in the U.S. had one million or more Hispanic residents.[20] Virginia had more than a half million Hispanics in 2013.[66] More studies are needed in states where Hispanics

constitute a rapidly growing ethnic minority group; health care access barriers might vary by

state.

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CHAPTER 3

Community-based Lifestyle Intervention for Underserved Hispanics with Type 2 Diabetes in Southwest Virginia

Ivette G. Valenzuela, MPH,BSN[1], Kathryn Hosig, PhD, MPH, RD[1], Carlos Evia, PhD[2], Elena Serrano, PhD[3], Eleanor Schlenker, PhD, RD[3], & Kerry Redican, PhD, MPH, CHES[1].

1. Department of Population Health Sciences

2. Department of English

3. Department of Human Nutrition, Foods and Exercise

Abstract

Diabetes prevalence for adults in the U.S. in 2012 was 9.3% overall, 7.6% for non-Hispanic whites, and 12.8% for Hispanics; the estimated percentage of adults with pre-diabetes in 2012 was 35% for non-Hispanic whites and 38% for Hispanics. Immigration status and language have been identified as barriers to access to health care in Hispanics. Community-based diabetes education programs delivered in faith-based settings have been successful in improving diabetes self-management.

Glycemic control is crucial to prevent complications and associated costs related to pre-diabetes and diabetes. The aims of this study were to increase awareness of diabetes risk among the Hispanic population; evaluate need for diabetes education among Hispanics; deliver and collect formative data for a community-based diabetes lifestyle intervention; and collect data regarding social determinants of health.

Methods. Hispanic adaptation of a Virginia Cooperative Extension (VCE) type 2 diabetes lifestyle intervention was first interpreted and adapted to Hispanic culture and then piloted in partnership with two Catholic churches.

Results. Of 60 Hispanic adults who participated in blood sugar screening, 75% did not have medical insurance; and 62% had A1c > 5.7%, 72% of whom were unaware of having high blood sugar. A1c decreased for all six participants who completed the pilot intervention.

Conclusions. A collaborative, culturally tailored VCE type 2 diabetes intervention can be widely disseminated and may increase diabetes awareness, prevent progression of pre-diabetes, and promote better glycemic control among Hispanics.

Keywords. Community-Based Participatory Research, Type 2 Diabetes Mellitus, Hispanic Americans, Social Determinants of Health, Social Cognitive Theory

In the U.S., diabetes mellitus (DM) affects almost 24 million people and is the seventh leading cause of death. DM is such a significant public health concern that Healthy People 2020 lists diabetes as a separate topic with specific goals and objectives, including (1) reducing the annual number of new cases of diagnosed diabetes in the population, (2) reducing the death rate among persons with diabetes, (3) improving glycemic control among persons with diabetes, and (4) improving lipid control among persons with diagnosed diabetes.[1] Exacerbating the problem is that racial and ethnic minority groups constitute 25% of all adult patients with diabetes in the US and represent the majority of children and adolescents with type 2 diabetes mellitus (T2DM).[1]

Hispanics became the largest U.S. minority in 2012, representing 17% of the population.[2] Diabetes prevalence for adults in the U.S. in 2012 was 9.3% overall, 7.6% for non-Hispanic whites, and 12.8% for Hispanics.[3] The prevalence of Hispanic adults with diabetes is expected to be approximately 20% by 2031.[4] The estimated percentage of adults with pre-diabetes in 2012 was 35% for non-Hispanic whites and 38% for Hispanics.[3] In 2012, the total estimated annual cost of diabetes was $245 billion overall and $50 billion for Hispanic Americans and expected to

rise to $514 billion and $110 billion, respectively, by 2025. [5,6] The risk of being diagnosed with

diabetes is 66% higher for Hispanics compared with non-Hispanic whites; this risk is even

greater in Hispanics from Mexico (87%) and Puerto Rico (94%).[7] Glycemic control is crucial to

prevent complications and associated costs related to pre-diabetes and diabetes. For each 1%

reduction in mean A1c, there is an associated risk reduction of 21% for deaths related to

diabetes, 14% for myocardial infarction, and 37% for microvascular complications.[8,9]

Bilingual diabetes self-management interventions have decreased A1c, LDL, and blood

pressure, and has increased self-efficacy and knowledge about physical activity and healthy

eating in Hispanics.[10,11] Family, religion, collectivism and sympathy are important in the

Hispanic culture and should be incorporated in the implementation of interventions targeting

Hispanics.[12-16] In particular, religion, family, and faith play a very important role in the lives of

most Latinos.[17,18] In 2002, 70% of Latinos in the U.S. were Roman Catholic.[18,19] Access to

healthcare varies for Hispanics depending on income, language, and immigration status.[20,21]

Culturally tailored T2DM interventions targeting Hispanics have been successful in a

variety of settings, including clinics [22-25,] universities[26-29,] community locations convenient to

participants[30-32,] and home visits[32-35,].Most of these interventions were culturally tailored, and

many included education in Spanish or incorporated lay community health workers. Some

addressed faith and spiritual beliefs or recruited participants from churches, but none were found

that recruited participants from churches and delivered the program in participants' home church.

One intervention provided diabetes education at a Catholic faith-based clinic and blended

Spanish and English language.[36] Interactive group sessions, goal-setting, diaries, education by a

dietitian, and language tailoring were among intervention strategies associated with significant

A1c improvement in Hispanic women according to a recent systematic literature review.[37]

The current study employed principles of community-based participatory research (CBPR)[38,39] to evaluate the feasibility and potential effects of reaching the Hispanic population with diabetes awareness, prevention, and management programming. More specifically, the project was conducted through an academic-community partnership between Virginia Cooperative Extension and Catholic churches facilitated by the Virginia Tech Center for Public Health Practice and Research. Study objectives were to collect data regarding social determinants of health, assess awareness of diabetes risk, evaluate the need for diabetes self-management intervention, and conduct a pilot intervention for Spanish-speaking Hispanic members of two Catholic churches in southwest Virginia. Results of the formative evaluation were used to further tailor the intervention to meet the needs of the Hispanic community.

Methods

Consistent with principles of CBPR[38,39],the project was initiated in response to requests from Virginia Cooperative Extension (VCE) Family and Consumer Sciences agents and local diabetes educators involved in implementing a VCE T2DM lifestyle intervention (Balanced Living with Diabetes – BLD) for a Spanish adaptation of the program. Particular emphasis was placed on recognizing the community as a full partner and building on community strengths and partnerships as described below. All research activities were approved by the Virginia Tech Institutional Review Board (Please see Appendix A).

BLD was translated and interpreted into Spanish (Hispanic Balanced Living with Diabetes – HBLD) by a bilingual El Salvadoran doctoral student in public health with training and credentials in medicine and nursing. Regional Catholic churches that offered services in Spanish were identified and recruited to participate. Three churches expressed interest in the

project. Each church identified a committee and/or coordinator to work with the research team to plan and coordinate project activities.

Coordinators suggested offering diabetes awareness activities to the Hispanic community prior to initiating the pilot HBLD programs. Therefore, blood sugar screening and healthy recipe testing were conducted at two Catholic churches with assistance from members of the third Catholic church prior to pilot HBLD programs at the two churches that hosted screening and recipe testing. Church coordinators determined appropriate dates and times for conducting blood sugar screening and recipe testing and advertised the opportunity to the entire Hispanic community via flyers, church bulletins, announcements during church services, and word of mouth (Please see Appendices B, C, D, and E). Screening and recipe testing were conducted after mass in Spanish on Sunday at both churches in February of 2014.

Blood sugar screening. The only exclusion criterion for blood sugar screening was being under 21 years of age. Participants signed informed consent forms for A1c testing and completed a short anonymous demographic questionnaire (sex, age, and ethnical/racial origin, educational level, having a primary care provider and health insurance, time since last visit to a doctor or health care provider, and previous diagnosis of high glucose levels or diabetes) prior to screening. Glycosylated hemoglobin (A1c) was used for blood sugar screening because it is a marker of long-term glucose control (approximately 3 months) and is not sensitive to state of fasting .[40,41] Approximately 5μl of blood was drawn via fingerstick and analyzed for A1c via kit (A1c Now+ Multi-test A1c System, Fisher Scientific, Waltham, MA). Participants were given a take home report that provided their screening results along with guidelines for A1c in normal, pre-diabetes, and diabetes ranges. Participants with A1c > 5.7% were encouraged to seek follow up care.

Recipe testing. Recipes to be tested for inclusion in HBLD were selected from those available through the National Diabetes Education Program.[42] Ingredients were provided to church members who agreed to prepare the dishes and bring them to church on the day of recipe testing. Anyone present after Spanish mass was eligible to taste the dishes. Participants were asked to complete a short anonymous evaluation form to indicate their level of preference for each dish (Please see Appendices N and O). Flavor, texture, and smell were graded from 1 (dislike a lot) to 5 (like a lot). Color was graded from 1 (very unappetizing) to 5 (very appetizing). Likelihood of preparing recipes at home was also ranked from 1 (definitely no) to 5 (definitely yes).

HBLD pilot. The HBLD pilot began approximately four months after A1c screening. Church coordinators at the two churches that participated in A1c screening recruited Spanish-speaking Hispanic community members who were at risk for diabetes or were pre-diabetic to attend HBLD classes and to participate in the research study. Eligibility criteria for research participation were age 21 or older and fluency in Spanish; participants were not excluded based on A1c level or church membership, and class participation was open to anyone who was interested.

HBLD is based on Balanced Living with Diabetes (BLD), adapted for Virginia Cooperative Extension (VCE) from Dining with Diabetes (DwD), originally developed by West Virginia Cooperative Extension.[43] Published articles have reported significant change in self-reported diabetes knowledge, self-efficacy, and behavior, but none have reported change in glycemic control.[43,44] BLD and HBLD are designed to address Social Cognitive Theory more fully by including more mastery experiences and directly addressing social support, goal setting, and monitoring.[45-47] Furthermore, additional emphasis is given to physical activity (stretching,

strength and aerobic training, and walking). The program is provided in four weekly classes that are approximately two and a half hours in length. A1c is measured at the first class (or baseline assessment session) and at a 3-month review/reunion class. Each session includes an interactive presentation by a local diabetes educator (Certified Diabetes Educator or Registered Dietitian) followed by demonstration and tasting of healthy recipes provided in the participant notebook. The local extension agent coordinates the program and conducts the food demonstration. Recipes are tested and tailored to the target population. Class topics include diabetes self-care and lifestyle change (nutrition and physical activity) to manage T2DM and to reduce risk of heart disease. The Plate Method is used to control portion size and carbohydrate intake.[48,49]

Demographic and outcome data were collected during the baseline assessment session and at the 3-month follow-up session. Data collection was supervised by a research team member to ensure adherence to protocol and compliance with protection of human subjects. Participants completed questionnaires in groups, and bilingual research staff circulated to provide assistance and read questions as needed.

Demographic data included age, sex, race/ethnicity, educational attainment and income level, age when diagnosed with high glucose level, pre-diabetes or diabetes, whether the person saw a doctor for diabetes treatment, whether the person took medication for treatment of diabetes (including type of medication), and whether the person had medical insurance and coverage of diabetes supplies and medications by insurance.

The primary outcome measure was A1c, measured as described previously. Height was measured without shoes to the nearest ¼ inch using a portable stadiometer (PE-AIM-101, Perspective Enterprises, and Portage, MI). Weight was measured in light clothing without shoes

to the nearest 0.2 pound using a portable digital scale (Tanita model BWB800S, Perspectives Enterprises, Portage, MI). Body mass index (kg/m^2) was calculated.

Diabetes self-care knowledge and behavior were measured with questions regarding frequency of A1c testing, foot exams, dilated eye exams, checking blood glucose levels, and taking diabetes medications as prescribed. Questions were taken from instruments available through the Virginia Department of Health Virginia Diabetes Prevention and Control Project. Knowledge related to curriculum content for HBLD was measured using questions adapted from those used in BLD. The Godin Leisure Time Physical Activity Questionnaire was used to measure self-reported physical activity.[50, 51]

Variables addressing SCT constructs, specifically outcome expectations, self-efficacy, self-regulation ,and social support, were measured using questions adapted from an instrument (Health Beliefs Survey) developed and validated in a variety of adult populations over a decade of research. [47, 52-56] Questions were tailored to reflect specific behaviors and foods targeted by the BLD/HBLD program such as using the Plate Method to control carbohydrate intake, controlling portion sizes, consuming at least five servings of fruits/vegetables and three servings of whole grains daily, using the Nutrition Facts label, engaging in at least 30 minutes of physical activity per day, etc. Similar modifications of the Health Beliefs survey have yielded reliable and valid instruments.[47, 52-56]

Process evaluation data were collected throughout the project and included attendance at HBLD sessions, HBLD content covered, recipes and activities included during class sessions, and program costs. An exit questionnaire was administered at the three-month follow-up session to assess participants' opinions about the program.

Results

A1c screening. Of 60 participants screened, 100% self-identified as Hispanic, 68% were female, and 64% were 40 years old or younger. Only 36% had a high school degree or higher; 34% had completed 6th grade or lower. Seventy-five percent did not have medical insurance. Over half of participants had A1C > 5.7% (Figure 1). Of these, 72% had never been told that they had pre-diabetes, diabetes, or high blood sugar.

Figure 1. A1c screening results.

A1c Results (n = 59)

15%

46%

39%

■ < 5.7% (normal range) ■ 5.7% - 6.4% (prediabetes range) ■ > 6.4% (diabetes range)
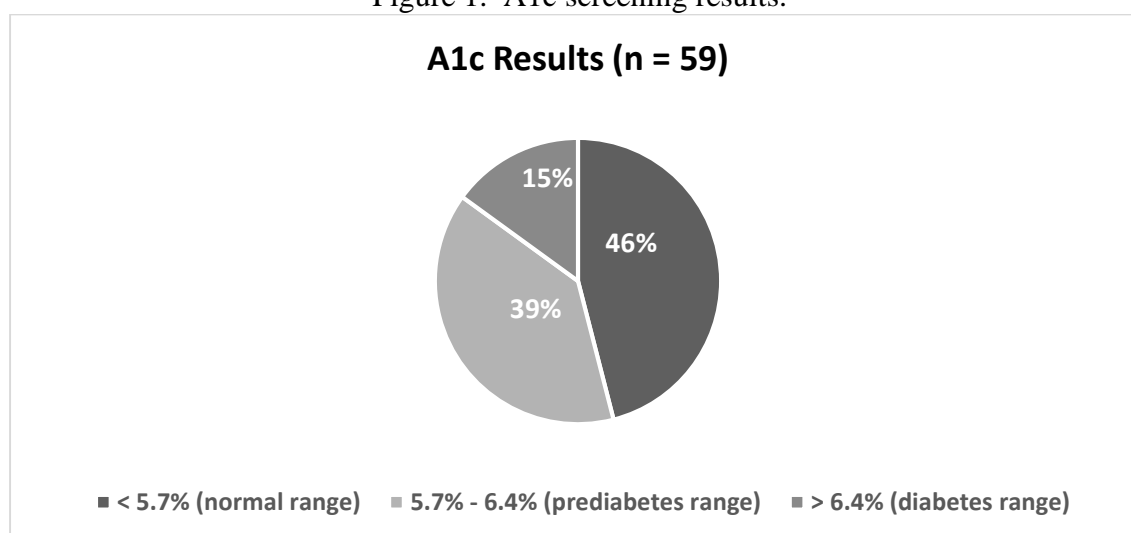
Recipe testing. All eight recipes tested were considered acceptable with scores of 4.5/5.0 or higher. Pozole (meat broth with vegetables), Fruits Fantasy (season fruit with light Greek yogurt and light orange juice), and Dos Quesos Pizza (two cheese pizza) were the most popular.

HBLD Pilot. Descriptive and outcome data are presented for the 16 participants from both churches combined. Baseline data (n=12) indicated that 75% did not have a high school degree or higher and 56% had annual income less than $30,000. Thirty-six percent of participants had baseline A1c indicative of pre-diabetes (between 5.7% and 6.4%), and 27% percent had baseline A1c indicative of diabetes (≥ 6.4%). None of them took insulin, and 25% took pills or other

medication for high blood sugar. None had ever participated in a diabetes class or support group before HBLD.

Sixty-four percent of participants indicated at baseline that they sometimes engaged in a regular activity long enough to work up a sweat. Thirty-three percent ate five portions of fruits and vegetables four or more times a week for the past three months. Forty-two percent ate three servings of whole grains a day three or more times a week for the past three months.

Six participants completed both baseline and 3-month follow-up data collection. Five participants (42%) attended all four classes and 56% attended at least three classes.

A1c. Of the six participants who completed baseline and follow-up data collection, two had baseline A1c indicative of diabetes and four had baseline A1c indicative of pre-diabetes. A1c decreased for both groups, with a greater decrease for participants with baseline A1c indicative of diabetes (Table 1).

Table 1. Formative Pilot Program. Three month A1C change

	A1c- Baseline	A1c- 3 months	A1c change
Type 2 diabetes (n=2)	9.8 ± 4.53	9.25 ± 0.78	0.55 ± 0.39
Pre-diabetes (n=4)	6.08 ± 0.28	5.93 ± 0.34	0.15 ± 0.11

Weight. Of the five participants who completed baseline and follow up weight collection, four lost weight. Mean weight change was -0.92 ± 1.43, and weight loss ranged from 0.4 pounds to 4.6 pounds.

Physical activity. There was no change in reported physical activity level for the four participants who completed the Godin questionnaire at both baseline and 3-month follow up. Fifty percent said at baseline and follow up that they did moderate exercise for more than 15 minutes five times a week or more. Fifty percent said at baseline and follow up that they sometimes engaged in any regular activity long enough to work up a sweat.

Diet. Five participants completed baseline and follow up questions regarding diet. The percentage of participants who said that they ate five servings of fruits and vegetables more than four times a week in the past 3 months increased from 20% at baseline to 80% at follow up. The percentage of participants who said that they ate three servings of whole grains a day more than three days per week in the past 3 months increased from 40% at baseline to 60% at follow up. The percentage of participants who said that they used the Plate Method to control portion size for at least one meal per day increased from 25% at baseline to 75% at follow up.

Self-Efficacy. Four participants completed baseline and follow up questions regarding self-efficacy for walking and eating small portions. The percentage of participants who said that they were sure or very sure that they could eat smaller portions of food on most days increased from 50% at baseline to 75% at follow up. The percentage of participants who said that they were very sure that on most days they could walk or exercise when they had other things to do increased from 20% at baseline to 50% at follow up.

Exit survey. Of eight participants who completed an exit survey, 100% said that having a Spanish-speaking educator was very important, 88% said that would participate if the program were taught in English and translated into Spanish by an interpreter, and 50% said that would not participate in the program if having health insurance was required.

Discussion

The current study was designed to provide formative evaluation for tailoring HBLD to meet the needs of the Hispanic community. Strong interest from Catholic churches serving the Hispanic population and participation in blood sugar screening and recipe testing by Spanish-speaking members of the churches substantiates the need for the program and the potential for successful dissemination to the target population through partnership with faith-based

organizations. Results of blood sugar screening indicate that a significant proportion of the Hispanic community may be at risk for diabetes or already have pre-diabetes or T2DM without being aware of their condition or having regular medical care. Providing family-based prevention and management services in a location where Hispanic community members already congregate naturally and trust is already present has potential to prevent T2DM and to detect and treat it early to reduce complications associated with poor glycemic control. [57, 58]

Education level, income, and access to care were low based on results from the screening. These characteristics suggest that programs for the Hispanic community should be provided at no or low cost, presented in Spanish, held in a community location convenient and accessible to prospective participants, and include simplified messages and achievable target behaviors that are culturally sensitive. Participants indicated preference for Spanish-speaking educators.

Participation was not limited to individuals with diagnosed diabetes or baseline A1c indicative of diabetes in order to provide information about the need for T2DM intervention and to be inclusive and welcoming to the target population. Sample size for participants with baseline A1c greater than 6.4% was therefore too small to evaluate potential effect size for A1c reduction. The observed reduction in A1c for participants with baseline A1c above 5.7% and observed weight loss are encouraging, however. Reported improvements in diet and self-efficacy for both diet and physical activity are similarly encouraging.

Two larger quasi-experimental studies with interventions and research design similar to the present study produced significant improvements in diabetes self-management self-efficacy and glycemic control (A1c level) in Spanish-speaking Hispanic/Latinos.[57,58] Thus, evaluating the approach used in this study with a larger number of sites and participants is warranted. Feasibility of dissemination for HBLD is higher than for most diabetes self-management

interventions for Spanish-speaking participants reported in the literature to date because the

infrastructure of Cooperative Extension facilitates systematic collaboration with community

partners, including churches, at the local level.

Acknowledgment

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CHAPTER 4

**A1C and Serum Lipid Outcomes for Hispanic Adults with Pre-diabetes and Type 2
Diabetes in a Community-based Lifestyle Intervention Program in Southwest Virginia**

Abstract

Objectives: To evaluate the need for diabetes education among Hispanics and to provide preliminary data for A1c, serum lipids, and social cognitive variables related to diabetes three months after implementation of HBLD.

Methods. A community-based type 2 diabetes lifestyle education curriculum was adapted to the Hispanic culture. Preliminary A1c screening was conducted in two Catholic churches followed by random assignment of the churches to treatment and delayed treatment condition.

Results. Of 67 preliminary screening participants, 49% had A1c > 5.7%. Baseline versus 3-month A1c (mean ± s.d.) for HBLD participants was 6.0 ± 0.5 versus 6.2 ± 0.7 for the delayed control group (n = 10) and 6.4 ± 0.9 versus 6.4 ± 0.9 for the intervention group (n = 11).

Implications. HBLD has potential to prevent progression of pre-diabetes to type 2 diabetes among underserved Hispanics by providing education to those who may not otherwise have access to these services. Larger and longer-term studies are warranted.

Introduction

In 2012, Hispanics became the largest racial/ethnic minority group, representing 17% of the U.S. population. This percentage is projected to increase to 31% in 2060.[1] The lifetime risk for Americans being diagnosed with diabetes is about 40%, with risk for Hispanics at more than 50%.[2] In 2012, diabetes prevalence for adults in the U.S. was 9.3% overall and 12.8% overall for Hispanics.[3] Diabetes prevalence in Hispanics varies by geographic origin; prevalence for Central and South Americans was 8.5%, 9.3% for Cubans, 13.9% for Mexican Americans, and 14.8%

for Puerto Ricans.[3] The estimated percentage of adults in the U.S. with pre-diabetes in 2012 was 35% for non-Hispanic whites and 38% for Hispanics.[3] Glycemic control is crucial to prevent complications and associated costs related to pre-diabetes and diabetes. Culturally and linguistically appropriate community interventions delivered to Hispanics at high risk for type 2 diabetes (T2DM) have been effective in decreasing weight and improving A1c and insulin resistance.[4, 5] Hispanic Balanced Living with Diabetes (HBLD) is a community-based T2DM lifestyle education program developed for Virginia Cooperative Extension. Formative pilot HBLD programs provided preliminary A1c data regarding potential effectiveness of HBLD.

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Research Design and Methods

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Study Design
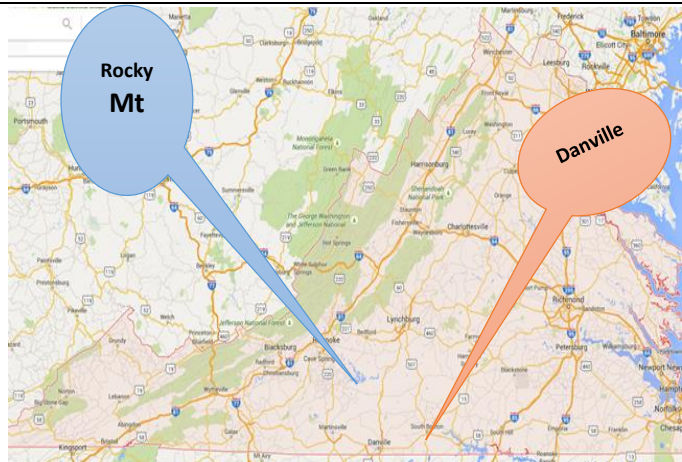
The study was a two-group randomized control trial (RCT) in which one church was randomly assigned to the treatment (HBLD) group and the other to delayed treatment condition. The delayed treatment church received HBLD after completion of 3-month follow up data collection. RCT is considered the gold standard of clinical research; RCT helps to eliminate confounding[6] and selection bias and "permits the use of probability theory to express the likelihood that any difference in outcome between treatment groups merely indicates chance" (Schulz & Grimes, 2002, p.516).

Blood glucose screening was offered at both churches prior to recruitment for the RCT. The research protocol was approved by the Virginia Tech Institutional Review Board (Please see Appendix P). Consent forms and questionnaires were available in both English and Spanish (Please see Appendices Q, R, S, T, U, V, and W).

The study applied the principles of community-based participatory research (CBPR)[7] and lessons learned from pilot HBLD programs conducted in 2013. The focus of the project was to

explore social determinants of health affecting the Hispanic community in Rocky Mount and

Danville, Virginia (Table 1), explore awareness of pre-diabetes and type 2 diabetes, assess serum

lipid levels, and assess feasibility of using community volunteers trained by Cooperative

Extension staff to provide nutrition education for children while parents participated in HBLD.

Participating churches were geographically located about 53 to 62 miles apart. Both churches

belong to the Richmond diocese and provided services in Spanish.

Table 1. Characteristics of Southwest Virginia cities participating in HBLD [8—11]

Region	City	% Hispanic Population 2013	Diagnosed Diabetes 2012
	Rocky Mount (Franklin County)	2.7% (Franklin County)	12.3% (Franklin County)
	Danville City	3.1%	14.1%

The research team developed partnerships with each church and worked with Hispanic

coordinators, Hispanic members of Catholic churches, and Virginia Cooperative Extension to

plan and coordinate HBLD activities. Previous interviews with Hispanic services coordinators

provided information about the feasibility of finding volunteers from the Hispanic community to

provide nutrition education for kids.

Participants

Church coordinators determined appropriate days and times for conducting A1c screening and

advertised the opportunity via flyers, announcements during church services, and word of mouth

to the entire Hispanic community. At both churches, preliminary A1c screening and diabetes awareness activities with the Hispanic community were conducted prior to initiating the HBLD programs.

Researchers recruited Spanish-speaking Hispanic participants of A1c screening (>5.7%) to attend HBLD classes and participate in the research study. Eligibility criteria for research participation were age 21 or older, Spanish-speaking, and have A1c 5.7% or higher. Class attendance was open to anyone who was interested.

Community-based type 2 diabetes educational intervention: HBLD

HBLD is based on Balanced Living with Diabetes (BLD), adapted for Virginia Cooperative Extension (VCE) from Dining with Diabetes (DwD) originally developed by West Virginia Cooperative Extension.[12] Published studies have reported significant change in self-reported diabetes knowledge, self-efficacy, and behavior with DwD, but none reported change in glycemic control.[12,13] BLD and HBLD are designed to address SCT more fully by including more mastery experiences and directly addressing social support, goal setting, and monitoring.[14-16] Furthermore, additional emphasis is given to physical activity (stretching, strength and aerobic training, and focus on walking). The program was provided in four weekly classes that were approximately two and a half hours in length. Each session included an interactive presentation by a local diabetes educator (Certified Diabetes Educator or Registered Dietitian), followed by demonstration and tasting of healthy recipes provided in the participant notebook. The local extension agent coordinated the program and conducted the food demonstration. Recipes were tested and tailored to the target population. Class topics included diabetes self-care and lifestyle change (nutrition and physical activity) to manage type 2 diabetes and to reduce risk of heart disease. The Plate Method was used to control portion size and carbohydrate intake.[17, 18]

Data collection

Qualitative and quantitative data were collected between the fall of 2014 and spring of 2015. The HBLD pilot had an initial baseline assessment and 3 month follow up assessment of body measures (BMI, A1c, and total cholesterol, LDL, HDL, and triglycerides). Data regarding social determinants of health, physical activity readiness, and some SCT variables were collected through questionnaires.

A1c. Glycosylated hemoglobin (A1c) was used as the measure for blood glucose control due to its characteristics of being a long-term glucose control marker and for not being sensitive to the state of fasting.[19, 20] When testing A1c, approximately 5µl of blood was drawn via fingerstick and analyzed for A1c via kit (A1c Now+ Multi-test A1c System, Fisher Scientific, Waltham, MA).[21] Participants were given a take-home report that indicated their screening result along with guidelines for A1C in normal, pre-diabetes, and diabetes ranges. Duplicate measures of A1c were taken; a third measurement was taken when the first two were more than 0.4 points different. Participants with A1c > 5.7% were encouraged to seek follow up care and were invited to participate in HBLD program.

Lipid panel. Serum lipids (total cholesterol, LDL, HDL and TG) were analyzed via kit (Alere Cholestech LDX® System).[22] About 40uL of blood was drawn via fingerstick for analysis.[22]

BMI. Height was measured without shoes to the nearest ¼ inch using a portable stadiometer (PE-AIM-101, Perspective Enterprises, Portage, MI). Weight was measured without shoes to the nearest 0.2 pound using a portable digital scale (Tanita model BWB800S, Perspectives Enterprises, Portage, MI).

SCT variables. SCT variables were measured using questions adapted from an instrument (Health Beliefs Survey) developed and validated in a variety of adult populations.[23-27]

Data analysis

Data were analyzed as described below. Statistical analysis was performed using SPSS (IBM, SPSS statistics 23).

Body measure variables. Change between baseline and three month follow up for body measure variables (A1c, serum lipids, body weight, BMI) between the treatment (HBLD) and delayed treatment control (HBLDd) groups were analyzed using Kruskal Wallis test for non-parametric variables (p < 0.05).

Knowledge and SCT variables. Change between baseline and three month follow up for SCT variables between HBLD and HBLDd were analyzed using Chi-square (p < 0.05) for knowledge variables and Kruskal Wallis (p < 0.05) for self-regulation, self-efficacy, and social support.

Results

Preliminary A1c screening.

Of 31 people screened at the treatment group (HBLD), 100% self-identified as Hispanic; 55% of screened participants had A1c > 5.7%. Of 35 people screened at the delayed treatment group (HBLDd): 100% self-identified as Hispanic; 43% of screened participants had A1c > 5.7%. The percentage of participants in each diabetes category is reported in Table 2.

Table 2 . Percentage of participants with A1c > 5.7 by diabetes status category.

Group	% of participant with A1c pre-diabetes range (5.7%-6.4%)	% of participant with A1c diabetes range (>6.5%)	% of participants with A1c > 7%
HBLD (n=31))	42%	3%	10%
HBLDd (n=35)	37%	11%	6%

Nutrition education for children

Participants at both churches were interested in nutrition education for children. However, only the treatment church was able to provide volunteers to be trained. Volunteers included two

high school students (one male and one female). Volunteers were trained to deliver a VCE curriculum for kids and then taught it while parents were participating in HBLD.

Participant Information

Of 11 people answering demographic questionnaire at HBLD group; 100 % self-identified as Hispanic. When asked, which of the following best describes you; none of them selected any possible option (African American, Caucasian, or Asian/Pacific Islander). Of 10 people answering demographic questionnaire in the HBLDd group; 100 % self-identified as Hispanic. When asked, which of the following best describes you only one participant selected Caucasian from possible options (African American, Caucasian, or Asian/Pacific Islander).

A1c

Baseline A1c versus 3-month A1c (mean ± s.d.) for HBLDd (n = 10) was 6.0 ± 0.5 versus 6.2 ± 0.7; for HBLD (n=11) was 6.4 ± 0.9 versus 6.4 ± 0.9. The change from baseline to follow up between churches was not statistically significant $(p = 0.5)$.

BMI

Baseline BMI versus 3-month BMI (mean ± s.d.) for delayed control group (n=10) was 31 ± 8 versus 30 ± 8; for the intervention group (n = 11) was 31± 3 versus 30 ± 5. The change from baseline to follow up between churches was not statistically significant $(p = 0.5)$.

Weight

Baseline weight versus 3-month cholesterol (mean ± s.d.) for HBLDd (n=10) was 174 ± 49 versus 173 ± 47; for HBLD (n = 11) was 159± 26 versus 160 ± 27. The change from baseline to follow up between churches was not statistically significant $(p = 0.5)$.

Cholesterol

Baseline cholesterol versus 3-month cholesterol (mean ± s.d.) for HBLDd (n=10) was 212 ± 44 versus 192 ± 40; HBLD (n = 11) was 184 ± 24 versus 196 ± 31. The change from baseline to follow up between churches was not statistically significant (p=0.07).

HDL

Baseline HDL versus 3-month HDL (mean ± s.d.) for HBLDd (n=9) was 42 ± 8 versus 44 ± 11; for HBLD (n = 10) was 48 ± 7 versus 46 ± 4. The change from baseline to follow up between churches was not statistically significant (p =0.46).

LDL

Baseline LDL versus 3-month cholesterol (mean ± s.d.) for HBLDd (n=9) was 141 ± 45 versus 122 ± 35; for HBLD (n = 10) was 109 ± 119 versus 115 ± 21. The change from baseline to follow up between churches was not statistically significant (p =0.2).

Triglycerides

Baseline cholesterol versus 3-month cholesterol (mean ± s.d.) for HBLDd (n=10) was 169 ± 75 versus 184 ± 116; for HBLD (n = 10) was 138± 49 versus 194 ± 176. The change from baseline to follow up between churches was not statistically significant (p =0.3).

Knowledge variables

Knowledge questions offered multiple choice answers; correct versus incorrect answers were compared at baseline and follow up. For completed baseline and follow up data collection; there were no statistically significant differences for change from baseline to follow up between churches. Baseline and 3-month follow up results for knowledge questions are included in Table 3.

Table 3. Baseline and 3-month Follow Up Knowledge for Intervention and Delayed Control Churches[1,2]

Question Text	Intervention baseline	Intervention 3-month	Delayed Control Baseline	Delayed Control 3-month
People with diabetes who are meeting their blood sugar goals should have their A1c checked at least __time(s) a year?.[2] Correct answer: 2 times a year	HBLD (n=4) 0%	HBLD (n=4) 0%	HBLDd (n=4) 50%	HBLDd (n=4) 25%
Most people with Type 2 diabetes should do moderate exercise, such as walking at least_?[2] Correct answer:30 minutes, 5 days a week	HBLD (n=9) 55%	HBLD (n=9) 89%	HBLDd (n=6) 50%	HBLDd (n=6) 100%
What size plate should you use to help you control your portion sizes?[2] Correct answer : 9 inches	HBLD (n=10) 0%	HBLD (n=10) 22%	HBLDd (n=6) 33%	HBLDd (n=6) 50%
Starchy foods (carbohydrates) should take up how much of your plate in the Plate Method?[2] Correct answer :One fourth	HBLD (n=9) 22%	HBLD (n=9) 67%	HBLDd (n=6) 17%	HBLDd (n=6) 67%
Non-starchy vegetables should take up how much of your plate at lunch and dinner in the Plate Method?[2] Correct answer :One half	HBLD (n=8) 38%	HBLD (n=8) 75%	HBLDd (n=7) 43%	HBLDd (n=7) 43%

[1] Expressed as percentage of participants with correct answer at baseline and at 3-month follow up

[2] No differences for change from baseline to 3-month follow up between churches (Chi Square, $p > 0.05$)

Self-efficacy variables.

When answering self-efficacy questions; possible answers were 1=very unsure, 2=unsure, 3= neither unsure nor sure, 4=sure, and 5=very sure. For completed baseline and follow up data collection, there was a statistically significant change from baseline to 3-month follow up between churches for one question (How sure are you that you can walk or exercise?). For the rest of the questions there were no statistically significant differences for change from baseline to follow up between churches. Baseline and 3-month follow up results are included in Table 4.

Table 4. Baseline and 3-month Follow Up Self-Efficacy for Intervention and Delayed Control Churches[1,2]

Question Text	Intervention baseline	Intervention 3-month	Delayed Control Baseline	Delayed Control 3-month
How sure are you that you can eat smaller portions of food?[2]	HBLD (n=8) 3.9± 1.1	HBLD (n=8) 3.5±1.5	HBLDd (n=8) 4.4 ± 0.5	HBLDd (n=8) 3.5 ± 1.1
How sure are you that you can eat meals at regular times?[2]	HBLD (n=8) 3.3 ± 1.2	HBLD (n=8) 4.3 ± 0.5	HBLDd (n=5) 4.0 ± 0.7	HBLDd (n=5) 4.4 ± 0.9
How sure are you that you can walk or exercise?	HBLD (n=8) 3.9 ± 1.1	HBLD (n=8) 4.1 ± 1.1	HBLDd (n=7) 4.6 ± 0.8	HBLDd (n=7) 4.1 ± 0.7
How sure are you that you can keep track of how much you walk or exercise?[2]	HBLD (n=9) 3.2 ± 1.1	HBLD (n=9) 3.7 ± 0.9	HBLDd (n=7) 4.1 ± 0.9	HBLDd (n=7) 3.7 ± 1.1

[1] Expressed as mean ± s.d. using scale from 1 to 5 with 1 = very unsure and 5 = very sure
[2] No differences for change from baseline to 3-month follow up between churches (Kruskal Wallis, $p > 0.05$)

Self-regulation variables

When answering self-regulation questions, possible answers to self-regulation questions were from zero to seven days per week. For completed baseline and follow up data collection, there were no statistically significant differences for change from baseline to follow up between churches. Baseline and 3-month follow up results are included in Table 5.

Table 5. Baseline and 3-month Follow Up Self-Regulation for Intervention and Delayed Control Churches[1,2]

Question Text	Intervention baseline	Intervention 3-month	Delayed Control Baseline	Delayed Control 3-month
How many days a week do you use the plate method?[2]	HBLD (n=8) 0.9 ± 1.8	HBLD (n=8) 3 ± 2.4	HBLDd (n=6) 0.5 ± 1.2	HBLDd (n=6) 1.0 ± 2.5
How many days a week do you eat meals at regular times?[2]	HBLD (n=10) 3.6 ± 2.1	HBLD (n=10) 4.9 ± 2.0	HBLDd (n=5) 6.0 ± 1.4	HBLDd (n=5) 5.8 ± 0.84
How many days a week do you walk or exercise?[2]	HBLD (n=10) 3.3 ± 2.4	HBLD (n=10) 4.0 ± 1.6	HBLDd (n=6) 3.0 ± 2.8	HBLDd (n=6) 2.7 ± 2.7
How many days a week do you keep track of how much you walked or	HBLD (n=9) 1.1 ± 2.3	HBLD (n=9) 2.2 ± 2.0	HBLDd (n=6) 1.2 ± 2.9	HBLDd (n=6) 0.83 ± 2.0

exercised during the week?[2]				
How many days a week do you make a plan to walk or exercise most days?[2]	HBLD (n=9) 2.4 ± 2.5	HBLD (n=9) 3.6 ± 1.4	HBLDd (n=6) 1.5 ± 2.8	HBLDd (n=6) 0.83 ± 1.6

[1] Expressed as mean ± s.d. using days a week from 0 to 7.

[2] No differences for change from baseline to 3-month follow up between churches (Kruskal Wallis, $p > 0.05$)

Social support variables

When answering social support questions, possible answers were 1= strongly disagree, 2= disagree, 3= neither, 4= agree, and 5= strongly agree. For completed baseline and follow up data collection; there were no statistically significant differences for change from baseline to follow up between churches. Baseline and 3-month follow up results are included in Table 6.

Table 6. Baseline and 3-month Follow Up Social Support for Intervention and Delayed Control Churches[1,2]

Question Text	Intervention Baseline	Intervention 3-month	Delayed Control Baseline	Delayed Control 3-month
The people close to me try to eat a healthy diet.[2]	HBLD (n=10) 3.3 ± 1.3	HBLD (n=10) 4.3 ± 0.9	HBLDd (n=8) 3.8 ± 1.0	HBLDd (n=8) 3.1 ± 1.3
The people close to me encourage me to get more exercise.[2]	HBLD (n=9) 3.6 ± 1.5	HBLD (n=9) 4.6 ± 0.5	HBLDd (n=7) 4.3 ± 0.5	HBLDd (n=7) 4.0 ± 1.0
The people close to me exercise or walk regularly.[2]	HBLD (n=9) 3.8 ± 1.3	HBLD (n=9) 4.0 ± 0.7	HBLDd (n=7) 3.1 ± 1.6	HBLDd (n=7) 3.0 ± 1.2
The people close to me encourage me to eat right.[2]	HBLD (n=9) 3.9 ± 1.2	HBLD (n=9) 4.2 ± 1.4	HBLDd (n=8) 4.1 ± 0.6	HBLDd (n=8) 4.0 ± 0.9

[1] Expressed as mean ± s.d. using scale from 1 to 5 with 1 = strongly disagree and 5 = strongly agree

[2] No differences for change from baseline to 3-month follow up between churches (Kruskal Wallis, $p > 0.05$)

Discussion

Lack of statistical significance for change in body measures is likely due to the small sample size. Potential for efficacy is demonstrated by change in the desired direction for HBLD versus

HBLDd. A1c did not increase over 3 months for HBLD participants compared to HBLDd participants. Preliminary data in a 5-year NIH-funded study with BLD has shown stronger effects on A1c for participants with A1c over 7.0, but results of this pilot study indicate potential to delay progression of pre-diabetes.

Changes in A1c and BMI observed in this study are consistent with reported changes in previous studies.[6,28-30] Changes in serum lipids were inconsistent between treatment groups and with expected treatment effects. This may be related to timing of the pilot RCT during the holiday season associated with less healthful eating and physical activity behaviors, although this explanation is not supported by the desired changes in A1c level and lack of expected differences between treatment and intervention groups. Of note is that the treatment group church provides breakfast every Sunday; breakfast includes pancakes, juice and cereal.

SCT (knowledge, self-regulation, social support, and self-efficacy) showed marked improvement in the intervention group. This improvement may lead to improved nutrition and physical activity habits over time, leading to improved A1c and serum lipid levels.

Every community has its own personality. When working with Catholic churches, it is important to approach every single Hispanic services coordinator in person. Hispanic services coordinators play an essential role in outreach to church members and to coordinate health programs activities. Churches have scheduled activities through the whole year; health programs need to adapt to church schedules and availability. As every church is different, the availability of volunteers to be trained may be different. Creation of partnerships between Hispanic services coordinators and institutions is necessary to reach members of the churches. This is consistent with needing strong grounding in principles of CBPR to facilitate effective partnership with churches to reach underserved populations.

Implications

HBLD is a culturally and linguistically appropriate intervention that has shown potential to prevent pre-diabetes progression to T2DM. When comparing baseline and 3-month follow up data, the treatment group showed an improvement in SCT variables as opposed to the delayed control group. This improvement might help to explain improvement in A1c level from baseline to three months for the treatment group compared with the delayed control group. The increased A1c levels at three months for the delayed treatment group suggest the need for more community-based interventions to stop the progression of pre-diabetes to diabetes. Developing and implementing culturally and linguistically interventions for Hispanics requires knowledge and understanding of Hispanic culture and barriers. As the Hispanic population continues to grow, stronger and expanded community-based approaches will be required. Creation of partnerships among agencies, organizations, and institutions that serve the Hispanic population will facilitate the processes of developing and implementing community based outreach, services and interventions.

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CHAPTER 5

Hispanic Balanced Living with Diabetes: Focus Groups

Abstract

During implementation of Hispanic Balanced Living with Diabetes (HBLD) in four Catholic churches in southwest Virginia, lack of awareness about abnormal glucose levels, low health literacy levels, and limited access to healthcare was noted.

Methods. Post-intervention focus group discussions were held with three groups of HBLD participants (total n = 25) to identify specific social determinants of health affecting Hispanics, assess participants satisfaction and suggestions for improvement of HBLD, and assess feasibility of recruiting and training volunteer community members as HBLD *promotoras*. Church coordinators and the educator recruited HBLD participants from three of the four churches that received HBLD.

Results: Participants identified patience and being bilingual as characteristics of effective *promotoras*. The need for financial compensation was identified as a barrier to recruiting community members as *promotoras*. Participants also described specific limited English proficiency and immigration status as barriers for accessing healthcare and health education classes. An effective culturally and linguistically appropriate model for promoting health and preventing chronic disease in Hispanic populations is needed to mitigate rising rates of diabetes and other lifestyle-related chronic diseases.

Key words: cultural and linguistic appropriate services, Extension, Hispanics, health promotion, chronic disease prevention.

In 2014, the Hispanic population in the U.S. was about 55 million (17.4 % of population). [1] Hispanics are expected to comprise 29% of U.S population by 2060.[2] Diabetes prevalence for adults in the U.S. in 2012 was 9.3% overall and 12.8% for Hispanics.[3] Diabetes became the fourth leading cause of death for Hispanics in the U.S. in 2013.[4] It is estimated that by 2031, 20.2% of adult Hispanics in the U.S. will have diabetes.[5] In the U.S., healthcare costs related to diabetes accounted for $245 billion in 2012; the uninsured paid 3.2% of medical expenses.[6] Diabetes, specifically type 2 diabetes, is a disease that has a lifestyle component in its causation. Type 2 diabetes (T2DM) accounts for about 95% of cases of diabetes in the U.S.[7]

Many Hispanics are faced with barriers including poverty, lack of health insurance, and limited English proficiency that negatively impact their health outcomes.[8] However, preventive care becomes a challenge for people who are uninsured. Among the barriers to T2DM diagnosis and management faced by the Hispanic population are lack of or limited English proficiency, low educational attainment, low socio-economic status, and lack of or reduced access to health care.[4]

Diabetes self-management education programs for Hispanics in Spanish-implemented in community settings have improved behavioral skills and glycemic control.[9] Education programs taught by bilingual educators have shown to improve diabetes outcomes [9-11] Positive outcomes on blood sugar control were shown in a *promotora*-led diabetes program for Latinas that was taught in Spanish and evaluated for feasibility, effectiveness, and acceptability.[12] These results demonstrated that developing culturally and linguistically appropriate initiatives is crucial to increase equity and to decrease ethnic and racial health care disparities.[13] Reaching diverse communities requires culturally sensitive approaches.[14]

In Southwest and Southeast Chicago, Illinois, diabetes education interventions were delivered by community health workers. Results of these two interventions showed improvement in glycemic control.[9, 10] In Lawrence, MA, community members were trained on diabetes prevention; A1c showed improvement as well.[11]

Lay health workers/*promotoras* are members of the community; *promotoras* share the same language and socioeconomic and cultural characteristics of the community that they are working with.[15] The role of the *promotora* includes delivering culturally and linguistically appropriate services and advocacy for patients. *Promotoras* assist with translation and interpretation of curricula and educate and mentor community members. [15]

Cooperative Extension has recognized the challenge of diversity and the importance of increasing the number of Family & Consumer Science (FCS) minority professionals.[16] It has also recognized the need for increasing professional development related to cultural competence for extension personnel .[16] The importance of increasing bilingual staff to reach the Latino community was also recognized by the North Carolina State University Extension as expanding the Latino market niche became a priority.[17] As extension has become more aware of Hispanic health and social and cultural needs, pilot programs that employ a *promotora* model for extension and Supplemental Nutrition Assistance Program Education (SNAP-Ed) to reach and provide services to this growing minority have provided promising results.[14,18,19]

The role of the *promotora* in understanding and reaching communities has been recognized for extension when delivering interventions to prevent birth defects in Hispanic children in South Texas.[14] *Promotoras* have been identified by the University of California Cooperative Extension as crucial members of the team to help them understand the Latino community when trying to

develop youth programs. [18] *Promotoras* have also worked with extension helping to deliver healthy home interventions concerning education about dangerous gases).[19]

Methods

To address health disparities faced by many Hispanics, a T2DM lifestyle intervention, Hispanic Balanced Living with Diabetes (HBLD), took place in Southwest Virginia between 2013 and 2014. Post-intervention focus group discussions were held to identify specific perceived barriers when accessing primary prevention and healthcare services and to assess the feasibility of recruiting and training members of the Hispanic community to become HBLD *promotoras.* Extension has used a *promotora* model in different settings. Data from focus group discussions with participants in HBLD on access to health services, nutrition, and physical activity, Hispanic Balanced Living with Diabetes, and essential characteristics of *promotora* programs are provided.

Description of type 2 diabetes lifestyle education program (HBLD)

HBLD is based on Balanced Living with Diabetes (BLD), adapted for the Virginia Cooperative Extension (VCE) from Dining with Diabetes (DwD), originally developed by West Virginia Cooperative Extension.[20] BLD and HBLD are designed to address SCT more fully by including more mastery experiences and directly addressing social support, goal setting, and monitoring.[21-23] Furthermore, additional emphasis is given to physical activity (stretching, strength and aerobic exercise, and walking). The program was provided in four weekly classes that were approximately two and a half hours in length. Each session included an interactive presentation by a local diabetes educator (Certified Diabetes Educator or Registered Dietitian), followed by demonstration and tasting of healthy recipes provided in the participant notebook. The local extension agent coordinated the program and conducted the food demonstration.

Recipes were tested and tailored to the target population. Class topics included diabetes self-care and lifestyle change (nutrition and physical activity) to manage type 2 diabetes and reduce the risk of heart disease. The Plate Method was used to control portion size and carbohydrate intake.[24, 25]

Post-intervention focus groups

Following the HBLD pilot intervention, focus group discussions were held at three Catholic churches to understand specific barriers to healthcare and health services faced by the participants and to assess satisfaction with HBLD.[26, 27] Recruitment of participants took place at Catholic churches where HBLD was held. The only selection criterion for participation in focus groups was participation in HBLD. Informed consent forms were provided in Spanish and read and explained to participants before starting each focus group session. No participant was forced to answer any question or participate in any part of the discussion Participants were provided with light refreshments and $10 cash in exchange for participation in this study. Research protocol was approved by the Virginia Tech Institutional Review Board (Please see Appendix X). Consent forms and questionnaires were available in both English and Spanish. Signed voluntary informed consent was obtained from all participants (Please see Appendices Y and Z).

Each focus group discussion was 60-90 minutes in duration and led by a native Spanish speaker and moderator and an assistant moderator. Standard focus group protocol was followed.[28] Field and content experts including bilingual researchers developed discussion questions. Each session was audio-recorded and field notes were taken. Question topics included access to health services, nutritional and physical activity education, satisfaction with HBLD, suggestions for improving the effectiveness of HBLD, and the feasibility of recruiting and training *promotoras* among community members. Sample questions are provided in Table 1.

Table 1. Sample focus group questions

Access to Health Services	Where do you go when you have questions about your health or your family's health?
Nutrition and Physical Activity	How do you and your family learn about healthy eating?
Hispanic Balanced Living with Diabetes	Do you think it would be okay if there was an English-speaking educator if there is someone at the class to translate into Spanish?
Promotora	Would you ask a Hispanic community member trained to be a *promotora* for help in finding medical care and nutrition information?

Data were collected through audiotape and field notes. The Spanish audio-recordings were transcribed verbatim and then interpreted into English independently line-by-line by two bilingual people. A research team member with expertise in conducting and analyzing focus group data reviewed and coded the English transcript and identified major themes related to access to health services, nutrition and physical activity, HBLD, and *promotoras*. A bilingual researcher reviewed the transcripts for quotes that fit into the previously identified themes. The quotes that best exemplified those themes were identified.

Results

A total of three focus groups were held in two southwest Virginia cities in March and April of 2015. A total of 25 individuals participated, with a range of eight to nine participants per focus group; 62% of participants were female. Major themes from focus group discussions are provided below. Table 2 includes quotes illustrating topics that most directly inform future efforts to address barriers to healthcare and access to services for Hispanics.

Access to health services

During conversation about healthcare access, participants emphasized limited English proficiency as a barrier for them to communicate with health professionals. Delayed access to

preventive health services was due to not having health insurance, cost of health services, and unknown real final costs of preventive health services. Quotes about perceived health access barriers are reported in Table 2.

Nutrition and Physical Activity

Lack of awareness about the importance of healthy food and physical activity compounded by lack of educational programs in Spanish and discrimination prevented participants from using nutrition or health education services. Examples of statements included: "The lady is racist; she told me that I needed my American identification," and " In the church they also asked for an American ID." Willingness to pay for accessible services is illustrated in Table 2.

HBLD

Participants indicated that having a Hispanic Spanish speaker as educator was important to facilitate ongoing communication; they also stated the importance of understanding Hispanic culture: "She understands habits of Hispanic people," and, "We feel more confident and can explain ourselves better," are examples. The value of having a Spanish speaker as educator is addressed in Table 2.

Promotora

Being bilingual and trustworthy are important characteristics for effective *promotoras*. Another characteristic that was important for the participant is patience: Examples include, "(they) must be patient with us," "Kindness that knows more on how to explain oneself and even children," and" Friendly and patient disposition." Recruiting and training a volunteer *promotora* may be difficult due to the characteristics that a *promotora* has to meet, such as being bilingual and being paid to do the work; commonly identified barriers to finding a *promotora* are reported in Table 2

Table 2. Focus group quotes

	Language	*Health insurance and health care costs*
Health education and nutritional services access	"I think that as Hispanics, if we do not speak English, we face a big obstacle. Sometimes at the hospitals there is no translators, and that makes it harder to find a doctor" "Sometimes if you speak not so good English, the doctor does not understand very well, they make you all the tests and they do not solve anything. I think that is the problem, communication".	"….it was approximately one year ago that I had to go, and then to register they put barriers. They ask you for insurance" "I think that medical insurance plays a high role here, because most of us do not have it and we look for places where we can pay with cash so that we do not have a coming bill to pay" "If the illness doesn't kill you, the resulting fright from viewing the bill surely will"
	Willingness to pay for healthcare and educational access as long as it is affordable	
	"Yes if the cost had not been high; a price that my husband could afford because I do not work" "Charge something but it depends on who can have access based on what it costs".	
Promotora and value of having a Spanish speaker educator	*Barriers to recruiting and training a community member as a volunteer promotora*	*Characteristics needed on a promotora and value of Spanish Speaker*
	"It would be required that that person has time and disposition" "It's not easy because people who have those characteristics generally have work and are very busy". it's not easy because people who have those characteristics generally have work and are very busy" "You'd have to pay them".	"Must be kind" "Must speak both languages" "We feel more confident and can explain ourselves better " "She understands us and we understand her" "It's that one identifies more with the person in Spanish; one feels more trusting".

Conclusion and Implications

While some Cooperative Extension programs already use the *promotora* model to deliver culturally and linguistically appropriate services targeting Hispanics[13 18 19], the model can be adopted nationwide to help to mitigate health disparities and increase equity among minorities. HBLD is a diabetes management program. *Promotoras* could enhance HBLD and increase its effectiveness by helping participants connect to health services. The HBLD program was taught by a native Spanish speaker educator in order to most fully deliver a culturally and linguistically appropriate intervention by interpreting and adapting the original BLD program to the Hispanic language and culture, rather than mere translation of materials Barriers to recruiting community members as *promotoras* should be considered before Cooperative Extension programs develop their own *promotora* programs. The characteristics of effective educators identified through this study can be used by Cooperative Extension programs to guide development and help avoid potential pitfalls when developing new programming targeting Hispanic populations. Hiring native Spanish speakers will not only ensure that accurate information is provided, but that educators are aware of culturally appropriate ways to deliver diabetes prevention programs. Participants may feel more trusting of educators they identify with and therefore be more receptive to information provided and willing to participate. Additionally, participants may feel more certain that their questions and the responses of educators are fully understood.

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Chapter 6

Summary, Conclusions, Implications, and Recommendations

As the U.S. Hispanic population continues to grow, the prevalence of diabetes and its related complications within the Latino community continues to increase. As of 2012, diabetes related health care costs in the U.S. totaled $245 billion dollars.[1] The projected future health care related costs will significantly exceed this figure if the rate of this disease is not slowed or halted.[2] This dissertation research has focused on the potential impact that culturally and linguistically appropriate services can have on the Hispanic community and the costs to the nation as a whole. HBLD has the potential to improve the quality of and life expectancy of this group by providing services that many do not have access to, while simultaneously providing cost savings to the country.

During the initial literature review for this study, it was found that Hispanics face significant barriers to obtaining adequate healthcare. These barriers became evident during the formative phase (pre-screening for pre-diabetes and diabetes mellitus), when participants reported that only 36% had a high school diploma or higher and 75% did not have health insurance. It is likely that this lack of health insurance was a contributing factor towards 72% of screening participants with A1c >5.7 % having never been told that they had pre-diabetes, diabetes, or high blood sugar.

The results of the HBLD formative pilot indicate that linguistically and culturally adapted interventions may help to decrease the progression of pre-diabetes to diabetes. Although the sample size was very small and differences were not statistically significant, A1c did decrease slightly for participants in the pre-diabetes and type 2 diabetes categories. This is important because each 1% reduction in A1c mean is associated with a risk reduction of 21% for diabetes related deaths, 14% for myocardial infarction, and 37% for microvascular complications.[3]

Weight loss is another important element necessary to reduce the risk for diabetes/pre-diabetes related complications. In this regard, the intervention had a positive impact on weight loss with a mean weight change of approximately one pound. Changes in both A1c and weight provide positive reinforcement to participants in order to increase self-efficacy for healthy eating and physical activity.

Another encouraging indicator pertains to self-regulation; improvements in eating habits (frequency of use of the Plate Method) and frequency of eating meals at regular times were observed in the HBLD group as opposed to a slight decrease (by comparison) in the HBLDd group. Also, HBLD participants reported a slight but insignificant improvement in social support compared to HBLDd participants.

Several participants brought family members or friends to class. The class is marketed to people with type 2 diabetes and their families to further address social support. Increased awareness can have a domino effect where knowledge is spread throughout the community: increased awareness of diabetes risk, management, and control may also help to decrease development of pre-diabetes and the progression of pre-diabetes to diabetes. Such education can not only affect the lives of participants, but can influence others in a community who are less likely to be aware of pre-diabetic and diabetic levels and whose related trajectory will be higher than the national average in the years to come.

A literature review revealed that limited English proficiency was a major barrier to health care and nutrition education access in the Hispanic community.[4] The value of having a Native Spanish speaking educator was highlighted during the post-intervention focus group discussion. However, the feasibility of recruiting and training a volunteer community member as a *promotora* was deemed difficult by the participants due the characteristics that a *promotora* has

to meet (being Hispanic, bilingual, and able to volunteer). Nevertheless, a *promotora* was recognized as an important liaison when educating and connecting members of the community to health care.

Recommendations

This study indicates that a collaborative, culturally tailored VCE type 2 diabetes intervention has the potential to be widely disseminated and may increase diabetes awareness, prevent progression of pre-diabetes, and promote better glycemic control among Hispanics with type 2 diabetes. This is important as many participants were unaware of their elevated A1c levels, possibly due in part to insufficient screening availability as a result of a lack of health insurance and education. Culturally and linguistically appropriate interventions have the potential of improving the lives of many while providing the nation with potentially significant health care related cost savings.

Education programs that raise health literacy can mitigate some or much of these costs if implemented throughout the country. This is especially applicable to the Hispanic community. Previous studies have shown that linguistically and culturally appropriate intervention programs improve glycemic control and anthropometric measures.[4-13] HBLD has provided the immediate measurable (and visible) outcome of weight loss for participants. This is especially noteworthy as the sample group included a high percentage of individuals who did not have a high school degree (or higher) and diabetes prevalence is higher among people with lower educational attainment.[14] Therefore, the need for health and nutrition education appears to be a priority among many Hispanics who appear to be subject to poverty and low educational attainment.[4]

Developing and implementing culturally and linguistically appropriate services will be key to outreach to this community. When educating and conducting outreach to the Hispanic

community, the use of the *promotora* model is crucial. Without these bridges for cultural and linguistic understanding, programs such as HBLD would likely lose some (or most) of their effectiveness. The barriers to health care that many Hispanics face make preventive programs an urgent need in order to decrease diabetes prevalence and its projected future costs.

HBLD was developed for Cooperative Extension. Extension has begun outreach to the Hispanic community, but additional, more systematic efforts are needed. Extension has programs for training community volunteers. Based on focus group discussion results, resources will need to be identified to provide compensation to Hispanic community members in order to facilitate recruitment, training, and retention of HBLD *promotoras*. The increased need for culturally and linguistically appropriate services also calls for increasing recruitment and training of Hispanics into Extension staff positions.[15]

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APPENDICES

Appendix A. Chapter 3 Institutional Review Board approval letter
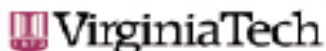
VirginiaTech

Office of Research Compliance
Institutional Review Board
North End Center, Suite 4120, Virginia Tech
300 Turner Street NW
Blacksburg, Virginia 24061
540/231-4606 Fax 540/231-0959
email irb@vt.edu
website http://www.irb.vt.edu

MEMORANDUM

DATE: February 3, 2014

TO: Dr. Kathryn Hosig, Ivette G Valenzuela

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires April 25, 2018)

PROTOCOL TITLE: A1C Screening Test for members of Holy Spirit and St.Gerard Churches

IRB NUMBER: 13-1057

Effective February 3, 2014, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

http://www.irb.vt.edu/pages/responsibilities.htm

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As:	**Expedited, under 45 CFR 46.110 category(ies) 2,7**
Protocol Approval Date:	**February 3, 2014**
Protocol Expiration Date:	**February 2, 2015**
Continuing Review Due Date*:	**January 19, 2015**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

———————————— *Invent the Future*

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
An equal opportunity, affirmative action institution

Appendix B. Recruitment material for formative and Pilot English version

Appendix C. Recruitment material for formative and Pilot Spanish version

Appendix D. Recruitment material for formative and Pilot English version

Balanced Living with Diabetes

❖ A free program for people with pre-diabetes and Type 2 diabetes and their families. This program has as a purpose to use the results of the study for a dissertation and publication.

❖ Goals
  ○ Manage your diabetes
  ○ Choose healthy foods
  ○ Be more active
  ○ Lower your blood sugar
  ○ Prevent complications

❖ Activities   : Blood sugar and fats fingerstick test.

  ○ Four weekly sessions and a 3 month reunion
  ○ Learn more about diabetes
    ▪ Get a kit with equipment and handouts to take home
  ○ Practice what you learn
    ▪ Set realistic goals
    ▪ Make plans that fit
    ▪ Keep track of your progress
    ▪ Check how you are doing
  ○ Try new recipes
  ○ Use a step-counter

Questions? Contact: Ivette Valenzuela   Phone number: 781-3306734

Appendix E. Recruitment material for formative and Pilot English version

ESTA INVITADO A PARTICIPAR EN VIDA BALANCEADA CON DIABETES EN ESPAÑOL

❖ Un programa GRATIS para las personas con pre-diabetes y diabetes tipo 2 y sus familias
❖ Objetivos:
o Controlar su diabetes
o Elegir comidas saludables
o Ser más activo
o Bajar los niveles de azúcar en la sangre
o Prevenir complicaciones
❖ Incluye:
o Cuatro sesiones semanales y una reunión a los 3 meses
o Un bolso con materiales de apoyo y folletos para llevar a casa.
o Degustación de nuevas recetas
o Un contador de pasos

¿CUANDO?
DOMINGO, 8, 15,22 y 29 de Junio
¿LUGAR?
IGLESIA HOLY SPIRIT
¿HORA?
DESPUES DE MISA DE 1PM
¿Preguntas?
Contacte a: Ivette Valenzuela
Correo Electrónico: ivettev@vt.edu celular: 781-330-6734

Appendix F. A1c Screening consent form for formative and pilot form English version

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants in Research Projects Involving Human Subjects

Title of Project: **A1c Screening Test for Members of NAME OF THE CHURCH**

Investigator(s): Kathy Hosig, PhD, MPH, RD   khosig@vt.edu/ **(540) 231-6637**
                     Name   **E-mail / Phone number**

              Ivette Valenzuela, MPH   ivettev@vt.edu **/ (540) 231-6637**
                     Name   **E-mail / Phone number**

I. Purpose of this Research Project
    This is a research project of Virginia Tech. It will help us know how many members of Holy Spirit and St. Gerard churches have blood sugar that is too high and could be helped with education to prevent or control diabetes. It will also give participants a good idea of their risk for prediabetes or diabetes so they can talk with their doctor if they need to. All members of either church who are age 21 or over are invited to participate. You do not have to be a member of either church to participate.

II. Procedures
     We will ask you to fill out some questions about yourself like age, whether you are Hispanic, how much education you have, and whether you have a doctor or health insurance. Your name will not be on this form. Your information will be anonymous. We just want to get an idea of how many people have each of these things but not who has them. These questions should take no more than 10 minutes to answer.
    We will test your blood sugar control with the A1c test. This is a measure of how much sugar is attached to your red blood cells. It shows how high your average blood sugar was over the past three months.
    A small, pointed lancet will be used to prick the tip of your finger, and a very small amount of blood will be taken into a small tube. This sample of blood will be put into a small machine, and your A1c number will be given about 5 minutes later. We will bring your number to you when it is ready. We will show you the number and let you know whether it is too high or not. You will keep a sheet of paper with your number on it compared to the recommended number.   We will not keep a copy of your number with your name on it. We will only keep this number on the page with your answers to the other questions. This page will not have your name on it.

Source: http://www.a1cnow.com/Professionals/A1CNow-Overview/procedure
If a researcher or other staff person is accidentally exposed to your blood, your blood will be tested for the presence of HIV, the Hepatitis Virus, and the Hepatitis C Virus. There will not be

any cost to you for this test. The research team will follow proper procedures for testing and reporting as outlined by Virginia State Law, which includes sending the blood sample to a certified laboratory. If your blood requires testing, you will be informed of your test results and provided with the opportunity to receive appropriate and timely counseling. Your results will also be sent to the local health department.

III. Risks

There is very low risk in having A1c screening test done. There may be a little bit of pain with the fingerstick. The lancet we use to prick your finger is designed not to make a big hole and to cause as little pain as possible. Your finger might continue to bleed for a few minutes after we take the blood sample. We will give you a bandage to stop the bleeding.

Only you will know your A1c number. We will not tell anyone else.

If your number is high, we will talk with you about places you can get medical help. You would be responsible for any expenses for medical care. The research project, research team or Virginia Tech cannot pay for medical care.

IV. Benefits

You will benefit from the A1c test by knowing if your blood sugar is high. If you know whether your blood sugar is high, you can seek help with controlling it. We will be offering a free diabetes education program at your church this spring that you can attend to help you learn how to control your blood sugar.

No promise or guarantee of benefits has been made to encourage you to participate.

V. Extent of Anonymity and Confidentiality

All of the information we collect from you will be anonymous. The only place we will have your name is on this consent form. We will use your contact information to let you know when the diabetes education program will be later this spring. The form with your personal information and your A1c number that we will keep will not have your name or contact information on it.

The Virginia Tech (VT) Institutional Review Board (IRB) may view the study's data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

VI. Compensation

You will not receive compensation for participation except for the A1c test that will be provided at no charge.

VII. Subject's Consent

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

_____ **Date**_____
Subject signature

_____
Subject printed name

VIII. Freedom to Withdraw

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free not to answer any questions that you choose or respond to what is being asked of you without penalty.

Please note that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

Should you withdraw or otherwise discontinue participation, you will be compensated for the portion of the project completed in accordance with the Compensation section of this document.

IX. Questions or Concerns

Should you have any questions about this study, you may contact one of the research investigators whose contact information is included at the beginning of this document.

Should you have any questions or concerns about the study's conduct or your rights as a research subject, or need to report a research-related injury or event, you may contact the VT IRB Chair, Dr. David M. Moore at moored@vt.edu or (540) 231-4991.

(Note: each subject must be provided a copy of this form. In addition, the IRB office may stamp its approval on the consent document(s) you submit and return the stamped version to you for use in consenting subjects; therefore, ensure each consent document you submit is ready to be read and signed by subjects.)

Appendix G. A1c screening consent form for formative and pilot Spanish version

VIRGINIA POLYTECHNIC INSTITU VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Consentimiento informado para Participantes en Proyectos de Investigación en Seres Humanos

Título del Proyecto: Prueba de detección A1c para miembros de las Iglesias NOMBRE DE LA IGLESIA

Investigador (es): Kathy Hosig, PhD, MPH, RD   khosig@vt.edu/ (540) 231-6637
Nombre   Correo electrónico / Número de teléfono
Ivette Valenzuela, MPH,BSN,RN   ivettev@vt.edu / (540) 231-6637
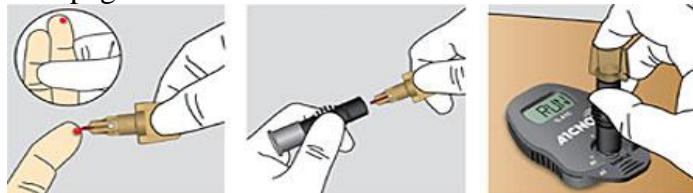**Nombre   Correo electrónico / Número de teléfono**

I. Objetivo de este proyecto de investigación
Este es un proyecto de investigación de Virginia Tech. Este proyecto de investigación nos ayudare a saber cuántos miembros de las Iglesias Sagrado Corazón, y San Francisco de Asís tienen niveles de azúcar altos, los cuales podrían ser ayudados con un programa educativo para prevenir o controlar la diabetes. Este proyecto de investigación también le dará a los participantes una idea de su riesgo de sufrir de prediabetes o diabetes, así ellos pueden hablar con su médico si necesitan hacerlo. Todos los miembros de las dos iglesias, que tienen 21 años o más están invitados a participar. No es necesario ser miembro de ninguna de las Iglesias para participar, todas las personas de 21 años o mayores están invitados a participar.

II. Procedimientos
Vamos a chequear los niveles de azúcar en su sangre con la prueba A1c. Esta prueba mide la cantidad de azúcar que está unida a sus glóbulos rojos y ensena que alto estaba su promedio de la azúcar en su sangre durante los últimos tres meses.
Una lanceta pequeña y puntiaguda será utilizada para pinchar la punta de su dedo, y una cantidad muy pequeña de sangre será tomada y puesta en un tubo. Esta muestra de sangre se coloca en una máquina pequeña, y su número de A1c se le dará unos 5 minutos más tarde. Vamos a traer a su número para que cuando esté listo. Le mostraremos su número y le haremos saber si es demasiado alto o no. Usted va a quedarse con una hoja de papel con su número y lo podrá comparar con el número recomendado. No vamos a guardar una copia de su número con su nombre en él. Sólo se guardara este número en la página con sus respuestas a las otras preguntas. Esta página no tendrá su nombre en él.

Source: http://www.a1cnow.com/Professionals/A1CNow-Overview/procedure

Si el investigador o el resto del personal se expone accidentalmente a su sangre, su sangre será analizada para detectar la presencia del VIH, el virus de la hepatitis y el virus de hepatitis C. No habrá ningún costo para usted para esta prueba. El equipo de investigación seguirá los procedimientos adecuados para la prueba y la presentación de informes como se indica por la Ley del Estado de Virginia, que incluye el envío de la muestra de sangre a un laboratorio certificado. Si su sangre requiere de pruebas, se le informará de los resultados de su prueba y proporcionará la oportunidad de recibir asesoramiento adecuado y oportuno. Sus resultados también serán enviados al departamento de salud local.

III. Riesgos

Existe un riesgo muy bajo al someterse a la prueba de detección A1c. Puede haber un poco de dolor con se le pincha el dedo. La lanceta que utilizamos para pinchar el dedo está diseñado para no hacer un agujero grande y para causar el menor dolor posible. Su dedo puede seguir sangrando durante unos minutos después de tomar la muestra de sangre. Le daremos una curita para detener el sangrado.

Sólo usted sabrá el número de su A1c. No le diremos a nadie.

Si el número es alto, vamos a hablar con usted sobre los lugares que usted puede conseguir ayuda médica. Usted será responsable de los gastos de atención médica. El proyecto de investigación, el equipo de investigación o Virginia Tech no pueden pagar la atención médica.

IV. Beneficios

Usted se beneficiará de la prueba A1c al saber si su azúcar en la sangre es alta. Si usted sabe si su nivel de azúcar es alto, puede solicitar la ayuda para controlarla. Vamos a ofrecer un programa de educación en diabetes gratis en su iglesia en esta primavera al cual usted puede asistir y podrá ayudarle a aprender cómo controlar su azúcar en la sangre.

Ninguna promesa o garantía de beneficios se ha hecho para animarle a participar**.**

V. Extensión de anonimato y confidencialidad

Toda la información que obtenemos de usted será anónima. El único lugar en que tendremos su nombre es en el formulario de consentimiento. Nosotros usaremos su información de contacto para hacerle saber cuándo se llevara a cabo el programa de educación en diabetes en adelante esta primavera. El formulario con sus datos personales y el número de su A1c que mantendremos no tendrá su nombre o datos de contacto.

La Junta de Revisión Institucional (IRB) de Virginia Tech (VT) puede ver los datos del estudio para fines de auditoría. El IRB es responsable de la supervisión de la protección de los sujetos humanos que participan en la investigación.

VI. Compensación

Usted no recibirá compensación por participación con excepción de la prueba A1c que se proporcionará sin cargo alguno.

VII. Consentimiento del Sujeto

He leído el formulario de consentimiento y condiciones de este proyecto. Todas mis preguntas ha sido contestadas. Por la presente reconozco lo anterior y doy mi consentimiento voluntario:

_____   **Fecha:_____**
Firma del sujeto

_____

Nombre escrito del sujeto

VIII. Libertad para retirarse
Es importante que usted sepa que usted es libre de retirarse de este estudio en cualquier momento sin penalización. Usted es libre de no responder a cualquier pregunta que usted elija o responder a lo que se pide de usted sin penalización.

Tenga en cuenta que puede haber circunstancias en las que el investigador puede determinar que un sujeto no debe continuar como sujeto.

En caso de retirarse o dejar de participar, será compensado por la parte del proyecto completado de acuerdo con la sección de Compensación de este documento.
IX. Preguntas o Preocupaciones
Si tiene alguna pregunta acerca de este estudio, puede contactar a uno de los investigadores cuya información de contacto se incluye al principio de este documento.
Si tiene alguna pregunta o preocupaciones sobre la forma que fue conducida este estudio o sus derechos como sujeto de investigación, o necesita reportar un evento o lesiones relacionadas con la investigación, puede comunicarse con el presidente de VT IRB Chair, Dr. David M. Moore at moored@vt.edu o (540) 231-4991.

(Nota: a cada sujeto se le deberá de proporcionar una copia de este formulario. Además, la oficina IRB puede estampar su aprobación en los documentos de consentimiento que presente y devolverla la versión estampada para su uso en sujetos adultos; por lo tanto, asegúrese que cada documento de consentimiento que se entregue esté listo para ser leído y firmado por temas.)

Appendix H. Data collection tools (English)
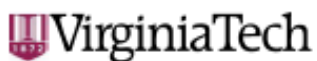
VirginiaTech

Balanced Living with Diabetes
Center for Research in Health Behavior
Department of Psychology (0274)
Blacksburg, Virginia 24061
(540) 231-9805
E-mail: bld@vt.edu

CHURCH NAME-VIRGINIA TECH
A1C Screening Test

Demographics:

1) How old are you? _____ years

2) Are you (circle one) ____ Male or ____ Female

3) Which of the following best describes you (check all that apply)? (Please check one)

____ African American
____ Caucasian
____ Asian/Pacific Islander
____ Other (please describe) _____

4) Are you Hispanic? (Please check one) _____ Yes _____ No

5) How many years of school have you completed? (Circle One)

1 2 3 4 5 6 7 8 9 10 11 12 Some College
College Graduate

Medical Information:
Do you have a family doctor? (Please circle Yes or No)
YES   NO

Do you have health insurance? (Please circle Yes or No)
YES   NO
Have you previously been diagnosed with Diabetes or pre-Diabetes or high sugar?
YES   NO

When was the last time you visited your doctor? (Please check one of the options)
___ 1 month ago   ___3 months ago   ___1 year   ___Over 1 year

A1C: _____

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Appendix I. Data collection tools (Spanish)

WVirginiaTech

Balanced Living with Diabetes
Center for Research in Health Behavior
Department of Psychology (0274)
Blacksburg, Virginia 24061
(540) 231-9805
E-mail: bld@vt.edu

Holy Spirit-VIRGINIA TECH
Prueba de A1C

Datos Demográficos:

1) ¿Qué edad tiene? _____ años

2) ¿Es usted (Por favor, marque uno) ____ Masculino o Femenino ____

3) ¿Cuál de lo siguiente le describe mejor (marque todo lo que corresponda)? (Por favor, marque uno)
____ Afroamericano
____ Europeo
____ Asiático / Islas del Pacífico
____ Otros (describa) _____

4) ¿Es usted Hispano? (Por favor, marque uno) _____ Sí _____ No

5) ¿Cuántos años de escuela ha completado? (Por favor, marque uno)

1 2 3 4 5 6 7 8 9 10 11 12   Algo de   Universidad
                              Universidad   de Graduados

Datos Médicos:

¿Tiene un médico de cabecera? (Por favor circule Si o No)

SI   NO

¿Tiene seguro médico? (Por favor circule Si o No)

Si   NO

¿Ha sido diagnostico anteriormente con Diabetes o casi Diabetes (al límite) o azúcar alta en la sangre? (Por favor circule Si o No)

Si   NO

¿Cuándo fue la última vez que visito a su médico? (Por favor marque una de las opciones)

___Hace 1 mes   ___Hace 3 meses   ___ Hace 1 año   ___ Más de 1 año

A1C: _____

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Appendix J. Take home form (English)

Take Home Report

Name: _____   **Date:** _____

A1c Results: _____

Diabetes Status	Your Results*	A1c Range**	Recommended Action
☐ Participant has been told by a healthcare provider they have diabetes	Your A1c screening test result is:	The A1c goal for most people with diabetes is: below 7%	☐ Share your results with your doctor at your next appointment ☐ Call your doctor to make an appointment because your A1c screening test was <u>above</u> 7% today
☐ Participant has been told by a healthcare provider they have prediabetes (borderline diabetes)	Your A1c screening test result is:	The A1c range for prediabetes is: 5.7% - 6.4%	☐ Share your results with your doctor and discuss ways to reduce your chances of developing type 2 diabetes
☐ Participant has NOT been told by a healthcare provider they have diabetes or prediabetes	Your A1c screening test result is:	Normal A1c is: below 5.7%	☐ Share your results with your doctor at your next appointment ☐ Call your doctor to make an appointment because your A1c screening test was <u>at or above</u> 5.7% today

*This A1c screening test was performed using a Bayer A1CNow+ analyzer and is not intended to diagnose diabetes or prediabetes.   Only your doctor can diagnose diabetes or prediabetes.
** Based on Standards of Medical Care in Diabetes, American Diabetes Association (2013)

Appendix K. Take home form (Spanish)

Roperte para llevar a casa.

Nombre:_____Fecha: _____

A1c Resultado : _____

| Estado Diabetico	Sus Resultados*	Rango A1c**	Accion Recomendendada
☐ Participante a sido informado por su proveedor de cuidado de salud que tiene diabetes	El resultado de su test de A1c es:	El objetivo de A1c para la mayoría de gente con diabetes es: Menos de 7%	☐Comparta este resultado con su doctor en su próxima cita.
			☐ Llame a su doctor para hacer una cita por que el resultado de su test de A1c fue mayor de 7% el día de hoy.
☐ Participante a sido informado por su proveedor de cuidado de salud que tiene pre-diabetes (casi diabetes)	El resultado de su test de A1c es:	El rango de A1c en prediabetes es: 5.7% - 6.4%	☐Comparta este resultado con su doctor y pregúntele acerca de maneras para disminuir la probabilidad de desarrollar diabetes tipo 2.
☐ Participante No A SIDO informado por su proveedor de cuidado de salud que tiene diabetes o prediabetes	El resultado de su test de A1c es:	A1c Normal es: Menos de5.7%	☐Comparta este resultado con su doctor en su próxima cita.
			☐ Llame a su doctor para hacer una cita por que el resultado de su test de A1c fue mayor de o mayor de 5. 7% el día de hoy.

* Esta prueba de detección de A1c se realizó con un analizador de Bayer A1CNow + y no está destinado a diagnosticar diabetes o prediabetes. Sólo su médico puede diagnosticar la diabetes o prediabetes.
** Basado en Normas de Atención Médica en Diabetes, Asociación Americana de la Diabetes (2013)

Appendix L. Doctor's letter for Formative and Pilot (English)

Virginia Cooperative Extension

A partnership of Virginia Tech and Virginia State University

VirginiaTech
College of Agriculture
and Life Sciences

VSU
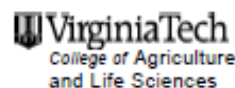
110 Hutcheson Hall
Virginia Tech
Blacksburg, VA 24061-0908
Voice Mail: 540-230-6787; Fax : 540-231-0762
E-Mail: schlenkr@vt.edu

June 25, 2012

Dear Doctor:

Your patient who is providing you with the results of a recent hemoglobin A1c is participating in a diabetes education program entitled Hispanic Balanced Living with Diabetes, presented by the Family and Consumer Sciences program of Virginia Cooperative Extension and Virginia Tech. Hispanic Balanced Living with Diabetes (HBLD) provides education to assist people with type 2 diabetes with the nutritional management of their disease. HBLD consists of four weekly classes of two hours each with a reunion class three months following, allowing for evaluation and reassessment. Each class consists of a slide program on healthy food choices and appropriate diabetes management presented by a local health professional, preparation and tasting of recipes suitable for persons with diabetes, a short discussion on ways to increase your physical activity through walking, and personal goal-setting. HBLD is a structured program with a set curriculum, handout materials, and recipes, designed to help participants gain confidence in managing their disease. Each participant receives a portion plate, a step-counter, a Plate Method place mat, and measuring cups to help in building new habits. The program is offered at no charge.

We evaluate the program using questionnaires and clinical measurements completed at the first class and the three-month reunion class. The questionnaires are intended to assess changes in food choices, diabetes management practices, and days including physical activity. Clinical measurements include hemoglobin A1c and Lipid Panel using a fingertip blood test. We provide participants with copies of the results of these clinical measurements, and encourage them to give a copy to their physician on their next visit. HBLD is viewed as a research project by the Virginia Tech Institutional Review Board for the Protection of Human Subjects, and the Consent Form and all study procedures have been approved by the Virginia Tech Office of Research Compliance.

If you would like any further information about this program, please be in touch with me (E-mail: schlenkr@vt.edu; Voice mail: 540-230-6787) or Dr. Kathy Hosig khosig@vt.edu We appreciate your interest in and support of this program.

Sincerely,

Eleanor D. Schlenker, PhD, RD,
Professor and Extension Specialist
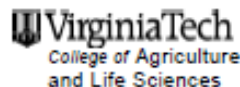Department of Human Nutrition, Foods, and Exercise

Appendix M. Doctor's letter for Formative and Pilot (Spanish)

Virginia Cooperative Extension
A partnership of Virginia Tech and Virginia State University

VirginiaTech
College of Agriculture
and Life Sciences

VSU

110 Hutcheson Hall
Virginia Tech
Blacksburg, VA 24061-0908
Voice Mail: 540-230-6787; Fax : 540-231-0762
E-Mail: schlenkr@vt.edu

Fecha:

Estimado Doctor:

Su paciente el cual le está proporcionando los resultados de una reciente medición de la hemoglobina A1c y está participando en un programa de educación en diabetes, titulado Vida Balanceada con Diabetes, presentado por el programa de la Familia y Ciencias del Consumidor de Virginia Cooperativa Extensión y Virginia Tech. Vida Balanceada con Diabetes en español (VBDE) proporciona educación para ayudar a las personas con diabetes tipo 2 con el manejo nutricional de su enfermedad.

VBDE consta de cuatro clases semanales de dos horas cada clase con una clase de reunión posteriormente a los tres meses, lo que permite la evaluación y reevaluación. Cada clase consiste en un programa de diapositivas sobre la elección de alimentos saludables y el manejo apropiado de la diabetes presentada por un profesional de salud local, la preparación y degustación de recetas aptas para personas con diabetes, un breve debate sobre la forma de aumentar su actividad física a través de caminar y establecimiento de metas personales . VBDE es un programa estructurado con un plan de estudios, materiales material de apoyo y recetas, diseñado para ayudar a los participantes a adquirir confianza en el manejo de su enfermedad. Cada participante recibe un plato para medir porciones, un contador de pasos, un mantelito, método del Plato y tazas de medir para ayudar en la construcción de nuevos hábitos. El programa se ofrece sin costo alguno.

Evaluamos el programa mediante cuestionarios y mediciones clínicas completadas en la primera clase y la clase de reunión luego de tres meses. Los cuestionarios están destinados a evaluar los cambios en la elección de alimentos, prácticas de manejo de diabetes, y los días que incluyeron actividad física. Las mediciones clínicas incluyen la hemoglobina A1c y panel de lípidos para el cual se utiliza un análisis de sangre obtenido al pinchar el dedo. Proporcionamos a los participantes con las copias de los resultados de estas mediciones clínicas, y les animamos a darle una copia a su médico en su próxima visita. VBDE es revisado como un proyecto de investigación por el Comité de Revisión Institucional de Virginia Tech para la Protección de Sujetos Humanos, y el formulario de consentimiento informado y todos los procedimientos del estudio han sido aprobados por la Oficina de Cumplimiento de Investigación de Virginia Tech.

Si desea más información respecto a este programa, por favor pongase en contacto conmigo: (correo electrónico schlenkr@vt.edu; Correo de voz: 540-230-6787) o Dra. Kathy Hosig khosig@vt.edu Apreciamos su interés y apoyo en este programa.

Sinceramente,

Eleanor D. Schlenker, PhD, RD,
Professor and Extension Specialist
Department of Human Nutrition, Foods, and Exercise

Appendix N. Recipe evaluation form (English)

Tasting these dishes is voluntary and anonymous. We will use this information to decide which recipes to include in our diabetes class. If you have food allergies, please look at the recipe to make sure there is nothing you are allergic to.

Rate the Food: Carne de Pavo

What do you think about the **Carne de Pavo**? Please, circle just one answer for each question.

1. Did you like the flavor of the food?

| Dislike a lot | Dislike some | Do not dislike or like | Like some | Like a lot |

2. Did you like the texture (mouthfeel) of the food?

| Dislike a lot | Dislike some | Do not dislike or like | Like some | Like a lot |

3. Do you think that the color of the food made the dish appetizing?

| Very un-appetizing | A little bit un-appetizing | Not sure | A little bit appetizing | Very appetizing |

4. Do you like the smell of the food?

| Dislike a lot | Dislike some | Do not dislike or like | Like some | Like a lot |

5. Do you think you would prepare this food at home?

| Definitely not | Probably not | Not sure | Maybe | Definitely yes |

Appendix O. Recipe evaluation form (Spanish)

La Degustación de estos platos es voluntaria y anónima. Usaremos esta información para decidir qué recetas incluiremos en nuestras clase de diabetes. Si tienes alergia a algún tipo de comida, por favor mire la receta para asegurarse de que no hay nada a lo cual es alérgico.

Califique la comida: Arroz con Pollo

¿Qué piensa usted acerca del **Arroz con Pollo**? Por favor, marque con un círculo una sola respuesta para cada pregunta.

1. ¿Te gustó el sabor de la comida?

No me gusto mucho   No me gusto algo   No me gusto O gusto   Me gusto un poco   Me gusto mucho

2. ¿Te gustó la textura (sensación en la boca) de la comida?

No me gusto mucho   No me gusto algo   No me gusto O gusto   Me gusto un poco   Me gusto mucho

3. ¿Cree usted que el color de los alimentos hizo que el plato apetitoso?

Muy Inapetecible   Un poco Inapetecible   No estoy seguro   Un poco Apetecible   Muy Apetecible

4. ¿Te gusta el olor de la comida?

No me gusto mucho   No me gusto algo   No me gusto O gusto   Me gusto un poco   Me gusto mucho

5. ¿Cree usted que desearía preparar este alimentos en casa?

Definitivamente No   Probablemente no   No estoy seguro   Tal vez   Definitivamente Si

Appendix P. Chapter 4 Institutional Review Board approval letter
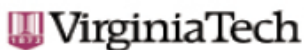
WVirginiaTech

Office of Research Compliance
Institutional Review Board
North End Center, Suite 4120, Virginia Tech
300 Turner Street NW
Blacksburg, Virginia 24061
540/231-4606 Fax 540/231-0959
email irb@vt.edu
website http://www.irb.vt.edu

MEMORANDUM

DATE: July 10, 2015

TO: Dr. Kathryn Hosig, Ivette G Valenzuela

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires April 25, 2018)

PROTOCOL TITLE: A1c and Lipid Panel Outcomes for Hispanic Adults with pre-diabetes and type 2 diabetes in a Community-based Lifestyle Intervention Program.

IRB NUMBER: 14-793

Effective July 10, 2015, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the Continuing Review request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

http://www.irb.vt.edu/pages/responsibilities.htm

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As:	Expedited, under 45 CFR 46.110 category(ies) 2,4,7
Protocol Approval Date:	**August 8, 2015**
Protocol Expiration Date:	**August 7, 2016**
Continuing Review Due Date*:	**July 24, 2016**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

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Appendix Q. Consent form for Pilot (English).

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Informed Consent for Participants
in Research Projects Involving Human Subjects

Title of Project: **A1c and Lipid Panel Outcomes for Hispanic Adults with pre-diabetes and type 2 diabetes in a Community-based Lifestyle Intervention Program.**

Investigator(s): Kathy Hosig, PhD, MPH, RD   khosig@vt.edu/ (540) 231-6637
      Name   E-mail / Phone number

                Ivette Valenzuela, MPH, BSN, RN   ivettev@vt.edu / (540) 231-6637
                    Name   E-mail / Phone number

I. Description of the Study:
Hispanic *Balanced Living with Diabetes* provides 4 weekly group classes and a 5th follow-up session in about 3 months. Classes are each about 2 ½ hours long. The classes are team taught by your local county Extension agent and a health care professional. Classes will include a discussion about healthy food choices and demonstrations of healthy cooking. You will get to taste all of the recipes that we prepare. We will also talk about increasing your physical activity and you will receive a step-counter to help you keep track of your steps each day.

II. Purpose of this Research Project
This is a research project of Virginia Tech which has as a purpose to use the results of the study for a dissertation and publication. It will help us know how many members of Sacred Heart and St. Francis of Assisi churches have blood sugar and fats that are high and could be helped with healthier eating and physical activity. This project is designed to test how well our program "*Hispanic Balanced Living with Diabetes*" helps people manage their pre-diabetes, type 2 diabetes and lipids through making changes in their eating and physical activity habits.

Anyone who is age 21 or over, has pre-diabetes or type 2 diabetes and speaks Spanish can be in the research project. People with Type 1 diabetes and family members can attend classes, but they will not be part of the research project. You do not have to be a member of either church to participate.

If you agree to be in the research project, you will participate in two assessment sessions: now, and in three months. The assessment sessions will last about 60 minutes.

III. Procedures
i. Assessments
We will take some body measurements, have you fill out some forms, and have you

keep track of your steps for one week each time we do an assessment; 2 times all together.

ii.   Body Measurements

We will measure your height, weight and A1C levels and Lipids. The A1C test is a measure of how much sugar is attached to your red blood cells. It shows how high your average blood sugar was over the past three months.

A small, pointed lancet will be used to prick the tip of your finger, and a very small amount of blood will be taken into a small tube. This sample of blood will be put into a small machine, and your A1c and blood fat numbers will be given about 5 minutes later. We will bring your number to you when it is ready. We will show you the numbers and let you know whether they are high or not. If your lipids or A1C values are high, we will make recommendations about follow-up or immediate health care, but we are not responsible for providing this care.

You will keep a sheet of paper with your number on it compared to the recommended number.   We will not keep a copy of your number with your name on it. We will only keep this number on the page with your answers to the other questions. This page will not have your name on it.

Source: http://www.a1cnow.com/Professionals/A1CNow-Overview/procedure

If a researcher or other staff person is accidentally exposed to your blood, your blood will be tested for the presence of HIV, the Hepatitis Virus, and the Hepatitis C Virus. There will not be any cost to you for this test. The research team will follow proper procedures for testing and reporting as outlined by Virginia State Law, which includes sending the blood sample to a certified laboratory. If your blood requires testing, you will be informed of your test results and provided with the opportunity to receive appropriate and timely counseling. Your results will also be sent to the local health department.

iii.   Forms

You will fill out a Participant Information form to tell us about yourself and what you usually eat. You will complete a Knowledge and Beliefs Survey to tell us what you know and believe about managing diabetes. You will complete a Leisure Time Physical Activity Questionnaire to tell us how active you are. We can help you fill out these forms, if you choose.

iv.   Step-Log

We will give you a step-counter (pedometer) which will be yours and will show you how to use it so you can keep a log of how many steps you take each day and how many minutes you walk each day for one-week**.**

v. If you don't want to answer all the questions or do all the measures

You are free to skip any question or skip any measure during assessments without penalty. Just leave the question blank or tell us you do not want to do a measure.

vi. If you miss a class

If you miss *Balanced Living with Diabetes* class, you can still come to all remaining classes.

vii. If you change your mind and do not want to be in the research project

You are free to withdraw from the research project at any time. Just tell a staff member you want to withdraw from the study. If you withdraw, all assessment materials collected from you will be destroyed. You may still attend classes, ask questions, join in food tastings, and receive class handouts if you decide to withdraw from the research project.

III. Risks

Your height, weight, blood fats and A1C will be measured during a group assessment session with as much privacy as possible. Still, you may feel embarrassed or uncomfortable during assessment. Only you will know your numbers. We will not tell anyone else.

There is very low risk in having A1c and blood fats screening test done. There may be a little bit of pain with the fingerstick. The lancet we use to prick your finger is designed not to make a big hole and to cause as little pain as possible. Your finger might continue to bleed for a few minutes after we take the blood sample. We will give you a bandage to stop the bleeding.

If your numbers are high, we will talk with you about places you can get medical help. You would be responsible for any expenses for medical care. The research project, research team or Virginia Tech cannot pay for medical care.

Filling out forms may be frustrating or cause a feeling of discomfort as you do them. Again, all information will be held in strictest confidence, and you do not have to answer any question that makes you uncomfortable.

IV. Benefits

You will benefit from the A1c and blood fats test by knowing if your blood sugar and blood fats are high. If you know whether your blood sugar and fats are high, you can seek help with controlling it. You will also receive free body measurements and feedback about your current body measurements and habits that may help you make changes to be healthier and reduce your risk of complications from pre-diabetes and diabetes.

By being in the research project you will help us evaluate whether the Hispanic Balanced Living with Diabetes classes worked at helping people with pre- diabetes and

type 2 diabetes control their blood sugar levels through improved nutrition and physical activity.

No promise or guarantee of benefits has been made to encourage you to participate.

V. Extent of Anonymity and Confidentiality

All of the information we collect from you will be anonymous. The only place we will have your name is on this consent form and a list of names that match study records so we can compare your measurements from one assessment with the next assessment without using your name. We will use your contact information to let you know when the diabetes education program will be later this spring. The form with your personal information and your A1c and blood fats numbers that we will keep will not have your name or contact information on it. It will only have your study number on it.

The Virginia Tech (VT) Institutional Review Board (IRB) may view the study's data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

VI. Compensation

You will not receive compensation for participation except for the A1C, blood fats test and body measurements that will be provided at no charge.

VII. Subject's Consent

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

_____ Date_____
Subject signature

_____
Subject printed name

_____
E-Mail   Phone number

_____
Address

VIII. Freedom to Withdraw

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free not to answer any questions that you choose or respond to what is being asked of you without penalty.

Please note that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

IX. Questions or Concerns

Should you have any questions about this study, you may contact one of the research investigators whose contact information is included at the beginning of this document.

Should you have any questions or concerns about the study's conduct or your rights as a research subject, or need to report a research-related injury or event, you may contact the VT IRB Chair, Dr. David M. Moore at moored@vt.edu or (540) 231-4991.

(Note: each subject must be provided a copy of this form. In addition, the IRB office may stamp its approval on the consent document(s) you submit and return the stamped version to you for use in consenting subjects; therefore, ensure each consent document you submit is ready to be read and signed by subjects.)

Appendix R. Consent form for Pilot (Spanish).

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Consentimiento Informando para Participantes en Proyecto de Investigación que envuelven Sujetos Humanos

Nombre del Proyecto: **Resultados de A1c y lípidos en Adultos Hispanos con pre-diabetes y diabetes tipo 2 en un Programa de Intervención Comunitaria basada en el Estilo de vida.**

Investigadoras: **Kathy Hosig, PhD, MPH, RD**   khosig@vt.edu/ **(540) 231-6637**
Nombre   E-mail / Número de Teléfono

Ivette Valenzuela, MPH, BSN, RN   ivettev@vt.edu **/ (540) 231-6637**
Nombre   E-mail / Número de Teléfono

IV.   Descripción del estudio:
Vida Balanceada con Diabetes ofrece 4 clases semanales de grupo y una quinta sesión de seguimiento en aproximadamente 3 meses.
Las clases son de aproximadamente 2 ½ horas de duración. Las clases son en equipo enseñadas por su agente de Extensión del condado y un profesional de la salud. Las clases incluirán una discusión acerca elección de alimentos saludables y demostraciones de cocina saludable. Usted probara las recetas que preparamos. También vamos a hablar sobre el aumento de su actividad física, y te daremos un contador de pasos para ayudar a mantener un registro de sus pasos cada día.

V.   Objetivo de este proyecto de investigación
Este es un Proyecto de Virginia Tech. Este nos ayudara cuantos miembros de las iglesias Sagrado Corazón y San Francisco de Asís tienen azúcar y grasa altos en la sangre; estas personas se podrían beneficiar con alimentación más saludable y actividad física. Este proyecto está diseñado para poner a prueba lo bien que nuestro programa "Vida Balanceada con Diabetes" ayuda a las personas a manejar su pre-diabetes, diabetes tipo 2 y lípidos a través de hacer cambios en su hábitos de alimentación y actividad física.
Cualquier persona de 21 años o más, tenga pre-diabetes o diabetes tipo 2 y hable español pueden participar en el proyecto de investigación. Las personas con diabetes tipo 1 y los familiares pueden asistir a clases, pero no van a formar parte del proyecto de investigación. Usted no tiene que ser un miembro de cualquiera de las iglesias para participar.
Si usted acepta participar en el proyecto de investigación, usted participará en dos sesiones de evaluación: ahora, y en tres meses. Las sesiones de evaluación tendrán una duración de unos 60 minutos.

VI.   Procedimientos
viii.   *Sesiones de Evaluación*

Tomaremos unas medidas corporales, le pediremos que llene algunos formularios y le pediremos que mantenga un registro de sus pasos por una semana cada vez que hagamos una evaluación; un total de dos veces.

ix.   **Medidas Corporales**

Vamos a medir su altura, peso, lípidos y los niveles de A1C. La prueba A1C es una medida de la cantidad de azúcar que se unió a las células rojas de la sangre y demuestra qué tan alto su promedio de azúcar en la sangre fue en los últimos tres meses.

Una lanceta pequeña y puntiaguda será utilizada para pinchar la punta de su dedo, y una cantidad muy pequeña de sangre será tomada y puesta en un tubo. Esta muestra de sangre se coloca en una máquina pequeña, y su número de A1c y grasa en la sangre se le darán unos 5 minutos más tarde. Le traeremos su número cuando esté listo. Le mostraremos su número y le haremos saber si es alto o no. Si su A1c y/o grasas son altos, le daremos recomendaciones de seguimiento o para que busque ayuda del médico inmediatamente, pero no somos responsables de proveerle estos cuidados.

Usted va a quedarse con una hoja de papel con su número y lo podrá comparar con el número recomendado. No vamos a guardar una copia de su número con su nombre en él. Sólo se guardara este número en la página con sus respuestas a las otras preguntas. Esta página no tendrá su nombre en él.

Source: http://www.a1cnow.com/Professionals/A1CNow-Overview/procedure

Si el investigador o el resto del personal se expone accidentalmente a su sangre, su sangre será analizada para detectar la presencia del VIH, el virus de la hepatitis y el virus de hepatitis C. No habrá ningún costo para usted para esta prueba. El equipo de investigación seguirá los procedimientos adecuados para la prueba y la presentación de informes como se indica por la Ley del Estado de Virginia, que incluye el envío de la muestra de sangre a un laboratorio certificado. Si su sangre requiere de pruebas, se le informará de los resultados de su prueba y proporcionará la oportunidad de recibir asesoramiento adecuado y oportuno. Sus resultados también serán enviados al departamento de salud local.

x.   **Formularios**

Tendrá que llenar un formulario de información del participante para decirnos acerca de usted. Usted va a llenar una forma de frecuencia de consumo para decirnos cuáles son los alimentos que generalmente come. Llevará a cabo una encuesta de conocimientos y creencias que nos diga lo que sabe y cree sobre el manejo de la diabetes. Deberá completar un Cuestionario de Actividad Física en su Tiempo Libre para saber su nivel de actividad. Podemos ayudarle a llenar estas formas, si lo desea

xi.   *Registro de Pasos*

Le daremos un contador de pasos y mostraremos cómo usarlo para que pueda

mantener un registro de la cantidad de pasos que da cada día y el número de minutos que camina todos los días durante una semana.

xii. ***Si usted no quiero contestar a todas las preguntas o hacer todas las medidas***

Usted es libre de saltar cualquier pregunta o saltar cualquier medida durante las evaluaciones sin penalización. Simplemente deje la pregunta en blanco o nos dice que usted no quiere hacer esa medida.

xiii. S*i pierdo o no vengo a una clase*

Si se olvida o falta a una clase de Vida Balanceada con Diabetes, puede continuar llegando a todas las clases restantes.

xiv. ***Si cambio de opinión y no quiero estar en el proyecto de investigación***
Usted es libre de retirarse de la investigación en cualquier momento. Simplemente dígale a un miembro del personal que desea retirarse del estudio. Si se retira, todos los materiales de evaluación recogidos de usted serán destruidos. Usted todavía puede asistir a clases, hacer preguntas, participar en degustaciones y recibir materiales de la clase aun si decide retirarse del proyecto de investigación

III. Riesgos
La talla, el peso, la grasa y la A1C sanguínea se medirán durante una sesión de evaluación en grupo con la mayor privacidad posible. Sin embargo, usted puede sentirse avergonzado o incómodo durante la evaluación. Sólo usted sabrá sus números. No le diremos a nadie.

Existe un riesgo muy bajo al hacerse las pruebas de detección A1c y grasa sanguínea. Puede haber un poco de dolor en la yema del dedo. La lanceta que usamos para pinchar el dedo está diseñado para no hacer un agujero grande y para causar el menor dolor posible. Su dedo puede seguir sangrando durante unos minutos después de tomar la muestra de sangre. Le daremos una curita para detener el sangrado.

Si los números son altos, vamos a hablar con usted sobre los lugares que usted puede conseguir ayuda médica. Usted sería responsable de los gastos de atención médica. El proyecto de investigación, el equipo de investigación o Virginia Tech no pueden pagar la atención médica.

Llenar formularios puede ser frustrante y causar una sensación de incomodidad cuando usted los hace. Una vez más, toda la información se llevará a cabo en la más estricta confidencialidad y usted no debe contestar ninguna pregunta que le haga sentir incómodo

VII.   Beneficios
Usted se beneficiará de la prueba A1c y grasa sanguínea al saber si su nivel de azúcar y grasa en la sangre son altos. Si usted sabe si su azúcar y grasa en la sangre son altos, usted puede buscar ayuda para poderlos controlarlos. También se le medirán sus medidas corporales y se le dará retroalimentación acerca de sus medidas corporales actuales y los hábitos que pueden ayudar a hacer cambios para ser más

saludable y reducir el riesgo de complicaciones de la pre-diabetes y diabetes.
Al estar en el proyecto de investigación usted ayudará a evaluar si las clases de Vida
Balanceada con Diabetes ayudaron a las personas con pre-diabetes y diabetes tipo 2
a controlar sus niveles de azúcar y lípidos en la sangre a través de una mejor nutrición
y actividad física.

Ninguna promesa o garantía de beneficios se ha hecho para animarle a participar.

V. Extensión de anonimato y confidencialidad

Toda la información que obtenemos de usted será anónima. El único lugar en que
tendremos su nombre es en el formulario de consentimiento y la lista que contiene su
nombre con número de participante, así podre comparar los resultados de sus medidas
de la sesión inicia y la de tres meses sin mira su nombre. Nosotros usaremos su
información de contacto para hacerle saber cuándo se llevara a cabo el programa de
educación en diabetes en adelante esta primavera. El formulario con sus datos
personales y los números de su A1c y grasa sanguínea que mantendremos no tendrá
su nombre o datos de contacto. Este solo se tendrá su número de participante.

La Junta de Revisión Institucional (IRB) de Virginia Tech (VT) puede ver los datos del
estudio para fines de auditoría. El IRB es responsable de la supervisión de la
protección de los sujetos humanos que participan en la investigación.

VI. Compensación

Usted no recibirá compensación por participación con excepción de la prueba A1c y
grasa sanguínea que se le proporcionará sin cargo alguno.

VII. Consentimiento del Sujeto

He leído el formulario de consentimiento y condiciones de este proyecto. Todas mis
preguntas han sido contestadas. Por la presente reconozco lo anterior y doy mi
consentimiento voluntario:

_____   Fecha: _____
Firma del sujeto

_____
Nombre escrito del sujeto

_____
Correo electrónico   Número de Teléfono

_____
Dirección

VIII. Libertad para retirarse

Es importante que usted sepa que usted es libre de retirarse de este estudio en cualquier momento sin penalización. Usted es libre de no responder a cualquier pregunta que usted elija o responder a lo que se pide de usted sin penalización.

Tenga en cuenta que puede haber circunstancias en las que el investigador puede determinar que un sujeto no debe continuar como sujeto.

IX. Preguntas o Preocupaciones

Si tiene alguna pregunta acerca de este estudio, puede contactar a uno de los investigadores cuya información de contacto se incluye al principio de este documento.

Si tiene alguna pregunta o preocupaciones sobre la forma que fue conducida este estudio o sus derechos como sujeto de investigación, o necesita reportar un evento o lesiones relacionadas con la investigación, puede comunicarse con el presidente de VT IRB, Dr. David M. Moore at moored@vt.edu o (540) 231-4991.

(Nota: a cada sujeto se le deberá de proporcionar una copia de este formulario. Además, la oficina IRB puede estampar su aprobación en los documentos de consentimiento que presente y devolverla la versión estampada para su uso en sujetos adultos; por lo tanto, asegúrese que cada documento de consentimiento que se entregue esté listo para ser leído y firmado por temas.)

Appendix S. Data collection- Body measures

Participant Number: _____   Date: _____

Body Measures

Pre-Test Measure

Test	Result	Assessed By (name)
A1c #1		
A1c #2		
A1c #3 if 1 &2 more than .4% apart		
Cholesterol		
Triglycerides		
LDL		
HDL		
BMI		

Body Mass Index Table

	Normal						Overweight					Obese									Extreme Obesity														
BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
Height (inches)															Body Weight (pounds)																					
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Source: Adapted from Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.

Appendix T. Data collection- Participant information (English)

Date: _____   Participant Number: _____
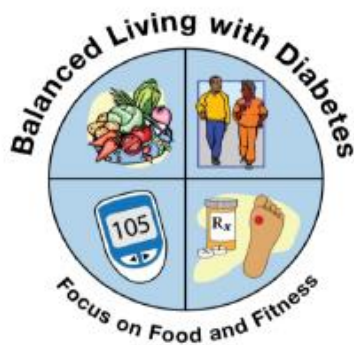
HISPANIC BALANCED LIVING WITH DIABETES

Participant Information

1

Date: _____ Participant Number: _____

Welcome to Hispanic Balanced Living with Diabetes! We hope this program will help you manage your diabetes. The information you share will help us make our program better. Feel free to skip any question and remember that all your information is kept confidential.

1) What is your current age? _____ years

2) What is your gender? _____ Male _____ Female

3) Which of the following best describes you (check all that apply)?

    _____ African American

    _____ Caucasian

    _____ Asian/Pacific Islander

    _____ Other (please describe) _____

4) Are you Hispanic?

    _____ Yes _____ No

5) How many years of school have you completed? (Circle One)

    1 2 3 4 5 6 7 8 9 10 11 12 Some   College
                                                College Graduate

6) What is the annual income of your household (include all adults working)?

    A. $10,000 or less/year   F. $50,001 - $60,000

    B. $10,001 - $20,000   G. $60,001 - $70,000

    C. $20,001 - $30,000   H. $70,001 - $80,000

    D. $30,001 - $40,000   I. $80,001 - $90,000

    E. $40,001 - $50,000   J. Greater than $90,000

Hispanic Balanced Living with Diabetes   Participant Number: _____

7)   Do you smoke or use tobacco products such as dip or snuff?

_____ Yes _____ No

8)   Do you have diabetes? (Please circle your answer)

A   Yes, Type II diabetes
B   Yes, Type I diabetes
C   No, my doctor says I am pre-diabetic
D   No, a family member has diabetes

9)   In the past year, did you see a doctor for diabetes?

_____ Yes   _____ No

10)   Do you take diabetes pills to control your blood sugar?

_____ Yes   _____ No

11)   Do you take insulin?

_____ Yes   _____ No

12)   What complications, if any, have you experienced with your diabetes?

_____bladder control problems   _____foot problems

_____nerve damage   _____low blood sugar

_____eye disease   _____kidney disease

_____sexual problems   _____stomach problems

Date: _____   Participant Number: _____

In the past week, how many days did you:

13) take your diabetes medications as directed by your doctor? (Circle the number of days)

0 1 2 3 4 5 6 7

14) check your blood sugar at least once? (Circle the number of days)

0 1 2 3 4 5 6 7

15) do a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate? *This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job.* (Circle the number of days)

0 1 2 3 4 5 6 7

16) use the Plate method to control your portion sizes for at least one meal - breakfast, lunch or dinner? (Circle the number of days)

0 1 2 3 4 5 6 7

17) skip checking your blood sugar or taking your diabetic medicines due to cost? (Circle the number of days)

0 1 2 3 4 5 6 7

18) How much of your diabetes supplies and medications are covered by insurance?

_____ None   _____ Most

_____ A little   _____ All

_____ Half   _____ Don't need them

4

Date: _____   Participant Number: _____

Circle the number that best describes how often you *typically* did these things related to managing your diabetes.

In the past 3 months, how many days a week did you normally ...	Days a week
19) eat 5 servings of fruits and vegetables a day?	0 1 2 3 4 5 6 7
20) eat 3 servings of whole grains a day?	0 1 2 3 4 5 6 7
21) eat meals at regular times each day?	0 1 2 3 4 5 6 7
22) eat 3 servings of milk or dairy a day?	0 1 2 3 4 5 6 7
23) walk or exercise?	0 1 2 3 4 5 6 7
24) avoid thinking about your diabetes because it upsets you?	0 1 2 3 4 5 6 7
25) keep track of how much you walked or exercised during the week?	0 1 2 3 4 5 6 7
26) make a plan to walk or exercise most days?	0 1 2 3 4 5 6 7
27) avoid taking care of your diabetes because you don't like thinking about it?	0 1 2 3 4 5 6 7

28) Have you ever participated in a diabetes education or support group besides Hispanic Balanced Living with Diabetes?

_____ Yes _____ No

If yes, from _____ to _____ (give dates you attended). If you've attended more than one group, give the dates for the most recent group.

How many times did the group meet between these dates? _____

5

Date: _____   Participant Number: _____

How confident are you that you can do different things to manage your diabetes? Circle or mark how sure you are.

How sure are you that on most days you can ...		Very Unsure	Unsure	Neither Sure or Unsure	Sure	Very Sure
29)	accept that diabetes is part of your life	Very Unsure	Unsure	Neither	Sure	Very Sure
30)	keep track of what you eat?	Very Unsure	Unsure	Neither	Sure	Very Sure
31)	eat smaller portions of food?	Very Unsure	Unsure	Neither	Sure	Very Sure
32)	eat meals at regular times?	Very Unsure	Unsure	Neither	Sure	Very Sure
33)	walk or exercise when you have other things to do?	Very Unsure	Unsure	Neither	Sure	Very Sure
34)	keep track of how much you walk or exercise?	Very Unsure	Unsure	Neither	Sure	Very Sure

Thank you for completing this survey!

Hispanic Balanced Living with Diabetes
Virginia Cooperative Extension
Virginia Tech
Blacksburg, VA 24061

Appendix U. Data collection- Participant information (Spanish)

Fecha: _____ Número de Participante: _____

Vida Balanceada con Diabetes

Información para el Participante

Fecha: _____ Número de Participante: _____

¡Bienvenido a Vida Balanceada con diabetes! Esperamos que este programa le ayudará a manejar su diabetes. La información que comparte nos ayudará a mejorar nuestro programa. Si quiere saltarse cualquier pregunta siéntase libre de hacerlo y recuerde que toda su información se mantiene confidencial.

1)	¿Cuál es su edad actual? _____ años

2)	¿Cuál es su género?	_____ Masculino	_____ Femenino

3)	¿Cuál de los siguientes mejor lo describe a usted (marque todos los que correspondan)?

   _____ Afroamericano

   _____ Europeo

   _____ Asiático / Islas del Pacífico

   _____ Otros (describa) _____

4)	¿Es usted Hispano? (Por favor, marque uno)	_____ Sí	_____ No

5)	¿Cuántos años de escuela ha completado? (Por favor, marque con un círculo su respuesta)

1 2 3 4 5 6 7 8 9 10 11 12	Algo de	Universidad
                                     	Universidad	Graduado

6)	¿Cuál es el ingreso anual de su hogar (incluye todos los adultos de trabajo)?

   A. $10,000 o menos / año	F. $50,001 - $60,000

   B. $10,001 - $20,000	G. $60,001 - $70,000

   C. $20,001 - $30,000	H. $70,001 - $80,000

   D. $30,001 - $40,000	I. $80,001 - $90,000

   E. $40,001 - $50,000	J. Mayor de $90,000

2

Vida Balanceada con Diabetes   Número de Participante: _____

7)   ¿Usted fuma o usa productos de tabaco, tales como mascando o inhalando tabaco?

_____ Sí   _____ No

8)   ¿Tiene diabetes o azúcar alta en la sangre? (Por favor marque con un círculo su respuesta)

A   Tengo diabetes tipo II
B   Tengo diabetes tipo I
C   Mi doctor dice que tengo pre-diabetes o estoy al límite de diabetes
D   Yo no tengo diabetes

9)   En el último año, ¿ha visto a un médico por la diabetes o azúcar alta en la sangre?

_____ Sí   _____ No

10)   ¿Usted toma pastillas para la diabetes para controlar su azúcar en la sangre?

_____ Sí   _____ No

11)   ¿Usted usa insulina?

_____ Sí   _____ No

12)   ¿Ha tenido alguna de estas complicaciones de la diabetes? (Marque todas las que apliquen)

____problemas de control de la vejiga   ___ problemas en los pies
___ daño a los nervios   ___ bajos niveles de azúcar en sangre
___ enfermedad de los ojos   ___enfermedad de los riñones
___ problemas sexuales   ___ problemas en el estómago

Fecha : _____   Número de Participante: _____

En la semana pasada, ¿cuántos días usted:

13)   tomó sus medicamentos para la diabetes como se lo indicó su médico? (marque con un círculo el número de días)

0   1   2   3   4   5   6   7

14)   revisó su azúcar la sangre al menos una vez? (marque con un círculo el número de días)

0   1   2   3   4   5   6   7

15)   hizo un total de 30 minutos o más de actividad física, lo que fue suficiente para elevar su frecuencia respiratoria? Esto puede incluir deporte, ejercicio y caminar a paso acelerado o andar en bicicleta para recreación o para ir y venir de los lugares, pero no debe incluir tareas del hogar o actividad física que puede ser parte de su trabajo. (marque con un círculo el número de días)

0   1   2   3   4   5   6   7

16)   uso el Método del Plato para controlar las porciones de al menos una comida? (marque con un círculo el número de días)

0   1   2   3   4   5   6   7

17)   omitió el control de su azúcar en sangre o de tomar sus medicamentos para la diabetes debido al costo? (marque con un círculo el número de días)

0   1   2   3   4   5   6   7

18)   ¿Qué parte de sus suministros para la diabetes y los medicamentos están cubiertos por el seguro?

_____ Ninguno   _____ La mayoría
_____ Un poco   _____ Todos
_____La mitad   _____ No los necesito

4

Fecha : _____   Número de Participante: _____

Circule el número que mejor describa con qué frecuencia típicamente suele hacer estas cosas relacionadas con el manejo de su diabetes.

En los últimos 3 meses, ¿cuántos días a la semana usted hizo normalmente …	Días de la semana
19) come 5 porciones de frutas y vegetales?	0 1 2 3 4 5 6 7
20) come 3 porciones de grano entero?	0 1 2 3 4 5 6 7
21) come las comidas a horas regulares?	0 1 2 3 4 5 6 7
22) come 3 porciones de leche o productos lácteos?	0 1 2 3 4 5 6 7
23) camina o hace ejercicio?	0 1 2 3 4 5 6 7
24) evita pensar en su diabetes porque te molesta?	0 1 2 3 4 5 6 7
25) leva un registro de cuánto usted caminó o hizo ejercicios durante la semana?	0 1 2 3 4 5 6 7
26) elabora un plan para caminar o hacer más ejercicios al día?	0 1 2 3 4 5 6 7
27) evita tomar cuidado de su diabetes porque no te gusta pensar en ello?	0 1 2 3 4 5 6 7

28) ¿Alguna vez ha participado en una formación o grupo de apoyo de la diabetes aparte de Vida Balanceada con diabetes?
_____ Sí   _____ No

En caso afirmativo, de cuando _____ a cuando_____ (indique las fechas a las que asistió). Si usted tiene asistió a más de un grupo, dar las fechas para el grupo más reciente.

¿Cuántas veces el grupo se reunió entre estas fechas?_____

Fecha : _____   Número de Participante: _____

How confident are you that you can do different things to manage your diabetes? Circle or mark how sure you are.

¿Qué tan seguro está usted de que puede ...	Muy Inseguro	Inseguro	No estoy seguro o inseguro	Seguro	Muy Seguro
29) aceptar que la diabetes es parte de su vida?	Muy inseguro	Inseguro	No estoy Seguro o inseguro	seguro	Muy seguro
30) llevar un registro de lo que come?	Muy inseguro	Inseguro	No estoy Seguro o inseguro	seguro	Muy seguro
31) comer porciones más pequeñas de alimentos?	Muy inseguro	Inseguro	No estoy Seguro o inseguro	seguro	Muy seguro
32) comer las comidas a horas regulares?	Muy inseguro	Inseguro	No estoy Seguro o inseguro	seguro	Muy seguro
33) caminar o hacer ejercicio cuando usted tiene otras cosas que hacer?	Muy inseguro	Inseguro	No estoy Seguro o inseguro	seguro	Muy seguro
34) llevar un registro de cuánto camina o hace ejercicio?	Muy inseguro	Inseguro	No estoy Seguro o inseguro	seguro	Muy seguro

¡Gracias por completar esta encuesta!

Vida Balanceada con Diabetes
Virginia Cooperativa Extensión
Virginia Tech
Blacksburg, VA 24061

Appendix V. Data collection- Knowledge and Health Beliefs (English)

Participant Number: _____   Date: _____

Balanced Living with Diabetes

Knowledge and Health Beliefs Survey

Balanced Living Knowledge

These questions ask about living with Diabetes. Place your answer or check-mark (✓) in the blank provided.

1. The A1c goal for people with diabetes is less than ___ % .

2. People with diabetes who are meeting their blood sugar goals should have their A1c checked at least _____ time(s) a year.

3. How often should people with Type 2 diabetes check their blood sugar (glucose)?

   ____ Every day   ____ Every week

   ____ Once a month   ____ Other

4. How often should people with diabetes get a dilated eye exam?

   _____ Every year   _____ Every 2 years

   _____ Every 3 years   _____ Other

5. How often should people with diabetes have a doctor examine their feet?

   _____ Every year   _____ Every 2 years

   _____ Every 3 years   _____ Other

6. Most people with Type 2 diabetes should do moderate exercise, such as walking at least:

   a. 10 minutes, 5 days a week   c. 30 minutes, 5 days a week

   b. 20 minutes, 5 days a week   d. 40 minutes, 5 days a week

| Balanced Living Knowledge |

7. Strength exercises to make muscles strong help people with Type 2 diabetes control their blood sugar levels.

   a. True   b. False

8. Walking is a great way to get enough exercise. What is the BEST way to build a walking program that you can stick to?

   a. walking with a friend

   b. walking in your neighborhood

   c. walking in the morning

   d. walk almost everyday and gradually make walks longer

9. Which fat is a good source of monounsaturated (healthy fat)?

   a. corn oil   c. margarine

   b. canola oil   d. butter

10. Which food has the most carbohydrates?

   a. turkey   c. corn

   b. broccoli   d. tomatoes

11. Which food has the most fiber?

   a. biscuits   c. white rice

   b. whole grain bread   d. cheese

Balanced Living Knowledge

12. Cake raises blood sugar more than bread raises blood sugar.

a. true   b. false

13. What size plate should you use to help you control your portion sizes?

a. 15 inches   c. 9 inches

b. 12 inches   d. 5 inches

14. Meat or protein should take up how much of your plate if you are using the Plate Method?

a. one half   c. one fourth

b. one third   d. less than one fourth

15. Starchy foods (carbohydrates) should take up how much of your plate in the Plate Method?

a. one half   c. one fourth

b. one third   d. less than one fourth

16. Non-starchy vegetables should take up how much of your plate at lunch and dinner in the Plate Method?

a. one half   c. one fourth

b. one third   d. less than one fourth

17. Which food has the most sodium?

a. fast food sandwich   c. fresh fruit

b. ground beef   d. fresh vegetables

4

Balanced Living Strategies

Tell us what you *typically* do and feel about your diabetes.

How many days a week do you …	Days a week
18. eat 5 servings of fruits and vegetables?	0 1 2 3 4 5 6 7
19. eat 3 servings of whole grain?	0 1 2 3 4 5 6 7
20. use the plate method?	0 1 2 3 4 5 6 7
21. eat meals at regular times?	0 1 2 3 4 5 6 7
22. eat 3 servings of milk or dairy?	0 1 2 3 4 5 6 7
23. avoid taking care of your diabetes because you don't like thinking about it?	0 1 2 3 4 5 6 7
24. walk or exercise?	0 1 2 3 4 5 6 7
25. keep track of how much you walked or exercised during the week?	0 1 2 3 4 5 6 7
26. make a plan to walk or exercise most days?	0 1 2 3 4 5 6 7
27. feel uncomfortable or unhappy that you have diabetes?	0 1 2 3 4 5 6 7

Balanced Living Social Support

Now, tell us about the people close to you – your family and closest friends. We want your opinion even if you are not sure. Circle or mark how much do you agree with the following?

The people close to me ...	Strongly Disagree 1	Disagree 2	Neither 3	Agree 4	Strongly Agree 5
28. try to eat a healthy diet.	1	2	3	4	5
29. do not eat chips or snack crackers.	1	2	3	4	5
30. believe whole grain and high fiber foods are important.	1	2	3	4	5
31. avoid regular sodas, sweet tea or any sugar sweetened beverages.	1	2	3	4	5
32. encourage me to get more exercise.	1	2	3	4	5
33. do not mention my diabetes because it upsets me.	1	2	3	4	5
34. exercise or walk regularly.	1	2	3	4	5
35. get upset when I talk about my diabetes.	1	2	3	4	5
36. believe exercise helps them manage their weight.	1	2	3	4	5
37. encourage me to eat right.	1	2	3	4	5

Balanced Living Confidence

How sure are you that you can, every day, do different things to manage your diabetes? Circle or mark how sure you are.

How sure are you that you can …		Very Unsure 1	Unsure 2	Neither Sure or Unsure 3	Sure 4	Very Sure 5
38.	accept that diabetes is part of your life?	1	2	3	4	5
39.	keep track of what you eat?	1	2	3	4	5
40.	eat smaller portions of food?	1	2	3	4	5
41.	eat meals at regular times?	1	2	3	4	5
42.	eat 3 servings of milk or dairy?	1	2	3	4	5
43.	eat 5 servings of fruits and vegetables?	1	2	3	4	5
44.	walk or exercise?	1	2	3	4	5
45.	walk or exercise when you have other things to do?	1	2	3	4	5
46.	keep track of how much you walk or exercise?	1	2	3	4	5
47.	walk or exercise when you are stressed or depressed	1	2	3	4	5

Balanced Living Expectations

Tell us what you think will happen when you make changes to manage your diabetes. Circle or mark how much do you agree that the following will happen?

If I make changes to manage my diabetes, I will ...	Strongly Disagree 1	Disagree 2	Neither 3	Agree 4	Strongly Agree 5
48. take too long to prepare meals	1	2	3	4	5
49. have to plan too far in advance	1	2	3	4	5
50. find it too stressful to think about my diabetes so much	1	2	3	4	5
51. spend too much time keeping track of foods	1	2	3	4	5
52. be overwhelmed thinking about what diabetes can do to my body	1	2	3	4	5
53. not have enough time for other things I want to do	1	2	3	4	5
54. have one more thing to worry about getting done	1	2	3	4	5
55. not like all the extra walking	1	2	3	4	5
56. have less time to spend with family	1	2	3	4	5
57. have to give up normal activities	1	2	3	4	5

Balanced Living Acceptance

Below you will find a list of statements about your thoughts and feeling about having diabetes and making healthy changes. *Mark the number that tells us how true each of the following is for you.*

How true is it for you?	Never True 1	Seldom True 2	Some-times True 3	Often True 4	Always True 5
58. When I have an upsetting thought or feeling about diabetes, I try to get rid of it.	1	2	3	4	5
59. I eat things I shouldn't when the urge is strong.	1	2	3	4	5
60. When I have negative feelings, I use food to make myself feel better.	1	2	3	4	5
61. I avoid thinking about what diabetes can do to my body.	1	2	3	4	5
62. I don't exercise regularly because I don't want to think about having diabetes.	1	2	3	4	5
63. Having diabetes makes me unhappy or uncomfortable.	1	2	3	4	5
64. I need to feel better about how I look to live the life I want to.	1	2	3	4	5
65. I don't believe that my diabetes will get that bad or hurt my body.	1	2	3	4	5
66. I don't like thinking about diabetes because someone I know died from diabetes.	1	2	3	4	5
67. I don't have what it takes to be healthy for life.	1	2	3	4	5
68. In order to eat well and exercise, I need to feel like it.	1	2	3	4	5

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Virginia Tech
Balanced Living with Diabetes
Center for Research in Health Behavior
Department of Psychology (0274)
Blacksburg, VA 24061

Thank You!

Appendix W. Data collection- Knowledge and Health Beliefs (Spanish)

Número de Participante: _____   Fecha: _____

Vida Balanceada con Diabetes

Encuesta sobre el conocimiento y creencias de salud

Conocimiento de Vida
Balanceada

Estas preguntas son acerca de vivir con Diabetes. Coloque su

respuesta o una marca de verificación (✓) en el espacio en blanco.

1. La meta de A1c para las personas con diabetes es menos de ____ %.

2. Las personas con diabetes que están cumpliendo con sus objetivos de

    azúcar en la sangre deben tener su A1c revisada al menos _____ vez

    (veces) al año.

3. ¿Con qué frecuencia deben las personas con diabetes tipo 2 revisar su

    azúcar en la sangre (glucosa)?

    _____ Todos los días   _____ Cada Semana

    _____ Una vez al mes   _____ Otra respuesta

4. ¿Con qué frecuencia las personas con diabetes deben hacerse un examen

    de los ojos con dilatación?

    _____ Cada año   _____ Cada 2 años

    _____ Cada 3 años   _____ Otra respuesta

5. ¿Con qué frecuencia las personas con diabetes deberían tener un médico que examine sus pies?

_____ Cada año   _____ Cada 2 años

_____ Cada 3 años   _____ Otra respuesta

6. La mayoría de las personas con diabetes tipo 2 deben hacer ejercicio moderado, como caminar, un mínimo de:

a. 10 minutos, 5 veces a la semana   c. 30 minutos, 5 veces a la semana

b. 20 minutos, 5 veces a la semana   d. 40 minutos, 5 veces a la semana

7. Ejercicios de fortalecimiento para los músculos ayudan a las personas con diabetes tipo 2 controlar sus niveles de azúcar en la sangre.

   a. Verdadero   b. Falso

> Conocimiento de Vida
> Balanceada

8. Caminar es una excelente forma de hacer suficiente ejercicio. ¿Cuál es la mejor manera de construir un programa de caminatas al que usted se puede apegar?

   a. caminar con un amigo

   b. caminar en su vecindario

   c. caminar en la mañana

   d. caminar casi todos los días y poco a poco hacer las caminatas más prolongadas

9. ¿Cuál es un ejemplo de una buena fuente de grasas mono insaturadas (grasas saludables)?

   a. aceite de maíz   c. margarina

   b. aceite de canola   d. mantequilla

10. ¿Qué alimento tiene el mayor número de carbohidratos

   a. pavo   c. maíz

   b. brócoli   d. tomate

Conocimiento de Vida Balanceada

11. ¿Qué comida tiene más fibra?

    a. Bizcochos (galletas)   c. arroz blanco

    b. pan de grano entero   d. queso

12. El pastel eleva el azúcar en la sangre más de lo que el pan aumenta azúcar en la sangre.

    a. Verdadero   b. Falso

13. ¿Qué tamaño de plato debe utilizar para ayudar a controlar los tamaños de las porciones?

    a. 15 pulgadas   c. 9 pulgadas

    b. 12 pulgadas   d. 5 pulgadas

14. ¿Qué cantidad de su plato ocupan la carne o proteínas si está utilizando el Método del Plato?

    a. La mitad   c. la cuarta parte

    b. La tercera parte   d. menos de la cuarta parte

Conocimiento de Vida Balanceada

15. ¿Qué cantidad de su plato ocupan los alimentos con almidón (carbohidratos) si está utilizando el Método del Plato?

a.   La mitad

c.   La cuarta parte

b.   La tercera parte

d.   Menos de la cuarta parte

16. ¿Qué cantidad de su plato ocupan los vegetales sin almidón en el almuerzo y cena, si está utilizando el Método del Plato?

a.   La mitad

c.   La cuarta parte

b.   La tercera parte

d.   Menos de la cuarta parte

17. ¿Cuál comida tiene la mayor cantidad de sodio?

a. Sándwich de comida rápida

c. Fruta fresca

b. Carne de res molida

d. Vegetales frescos

Vida Balanceada - Estrategias

Díganos lo que **normalmente** hace y siente acerca de su diabetes.

¿Cuántos días a la semana usted …	Días a la semana
18. come 5 porciones de frutas y vegetales?	0 1 2 3 4 5 6 7
19. come 3 porciones de grano entero?	0 1 2 3 4 5 6 7
20. usa el método del plato?	0 1 2 3 4 5 6 7
21. come las comidas a horas regulares?	0 1 2 3 4 5 6 7
22. come 3 porciones de leche o productos lácteos?	0 1 2 3 4 5 6 7
23. evita tomar cuidado de su diabetes debido a que no le gusta pensar en ello?	0 1 2 3 4 5 6 7
24. camina o hace ejercicio?	0 1 2 3 4 5 6 7
25. Hace un registro de cuánto usted caminó o se ejercitó durante la semana?	0 1 2 3 4 5 6 7
26. hace un plan para caminar o hace ejercicio casi todos los días?	0 1 2 3 4 5 6 7
27. se siente incómodo o infeliz porque usted tiene diabetes?	0 1 2 3 4 5 6 7

Vida Balanceada - Apoyo Social

Ahora, díganos acerca de las personas cercanas a usted - su familia y amigos más cercanos. Queremos su opinión, incluso si usted no está seguro. Marque cuánto está de acuerdo con lo siguiente

Las personas cercanas a mí ...	Fuertemente en Desacuerdo 1	Desacuerdo 2	Ninguno 3	De Acuerdo 4	Fuertemente en Acuerdo 5
28. tratan de comer una dieta saludable.	1	2	3	4	5
29. No comen papas fritas o galletas saladas.	1	2	3	4	5
30. creen que granos integrales y alimentos ricos en fibra son importantes.	1	2	3	4	5
31. evitan las sodas regulares, té dulce o cualquier azúcar bebidas endulzada con azúcar.	1	2	3	4	5
32. me animan a hacer más ejercicio.	1	2	3	4	5
33. no hablan de mi diabetes, ya que eso me molesta.	1	2	3	4	5
34. hacen ejercicio o caminan regularmente.	1	2	3	4	5
35. se molestan cuando hablo de mi diabetes.	1	2	3	4	5
36. creen que ejercicio les ayuda a controlar su peso.	1	2	3	4	5
37. me animan a comer bien/correcto.	1	2	3	4	5

Vida Balanceada-Confidencia

¿Qué tan seguro está usted de que es posible, todos los días, hacer cosas diferentes para manejar su diabetes? Marque lo seguro que usted está.

¿Qué tan seguro está usted de que puede ...		Muy Inseguro 1	Inseguro 2	No estoy seguro o inseguro 3	Seguro 4	Muy Seguro 5
38.	aceptar que la diabetes es parte de su vida?	1	2	3	4	5
39.	llevar un registro de lo que come?	1	2	3	4	5
40.	comer porciones más pequeñas de alimentos?	1	2	3	4	5
41.	comer las comidas a horas regulares?	1	2	3	4	5
42.	comer 3 porciones de leche o productos lácteos?	1	2	3	4	5
43.	comer 5 porciones de frutas y vegetales?	1	2	3	4	5
44.	caminar o hacer ejercicio?	1	2	3	4	5
45.	caminar o hacer ejercicio cuando usted tiene otras cosas que hacer?	1	2	3	4	5
46.	llevar un registro de cuánto camina o hace ejercicio?	1	2	3	4	5
47.	caminar o hacer ejercicio cuando está estresado o deprimido	1	2	3	4	5

Vida Balanceada -Expectativas

Díganos lo que usted piensa que sucederá cuando realice cambios para manejar su diabetes. Marque cuánto usted está acuerdo en que lo siguiente ocurrirá?

| Si hago cambios para manejar mi diabetes, yo voy a ...	Fuertemente en Desacuerdo 1	Desacuerdo 2	Ninguno 3	De Acuerdo 4	Fuertemente en Acuerdo 5
48. tomar mucho tiempo para preparar comidas	1	2	3	4	5
49. tener que plan con demasiada anticipación	1	2	3	4	5
50. encontrar demasiado estresante pensar mucho acerca de mi diabetes	1	2	3	4	5
51. dedicar demasiado tiempo para llevar un registro de los alimentos	1	2	3	4	5
52. sentirme abrumado(a) pensando acerca de lo que la diabetes puede hacer a mi cuerpo	1	2	3	4	5
53. no tener suficiente tiempo para otras cosas que quiero hacer	1	2	3	4	5
54. tener una cosa más de preocuparme por esto	1	2	3	4	5
55. no gustarme caminar adicionalmente	1	2	3	4	5
56. tener menos tiempo para estar con mi familia	1	2	3	4	5
57. tener que renunciar a mis actividades normales	1	2	3	4	5

Vida Balanceada - Aceptación

A continuación encontrará una lista de afirmaciones sobre sus pensamientos y sentimientos acerca de tener diabetes y hacer cambios saludables. Marque el número que nos dice cuán verdadera es cada una de las siguientes opciones para usted.

¿Qué tan cierto es esto para usted?	Nunca es Verdadero 1	Pocas veces verdadero 2	Algunas veces verdadero 3	A menudo es Verdadero 4	Siempre es Verdadero 5
58. Cuando tengo un pensamiento o sentimiento inquietante acerca de la diabetes, yo trato de deshacerme de él.	1	2	3	4	5
59. Yo como cosas que no debería, cuando el impulso es fuerte.	1	2	3	4	5
60. Cuando tengo sentimientos negativos, uso comida para sentirme mejor.	1	2	3	4	5
61. Evito pensar en lo que la diabetes puede hacerle a mi cuerpo.	1	2	3	4	5
62. No hago ejercicio regularmente porque no quiero pensar en tener diabetes.	1	2	3	4	5
63. Tener diabetes me hace infeliz o incómodo.	1	2	3	4	5
64. Necesito sentirme mejor acerca de cómo me veo para vivir la vida que quiero.	1	2	3	4	5
65. No creo que mi diabetes tendrá que hacerle daño a mi cuerpo.	1	2	3	4	5
66. No me gusta pensar en la diabetes porque alguien que conozco murió de diabetes.	1	2	3	4	5
67. No tengo lo que se necesita para estar saludable de por vida.	1	2	3	4	5
68. Para comer bien y hacer ejercicio, tengo que tener ganas de hacerlo.	1	2	3	4	5

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Virginia Tech
Vida Balanceada con Diabetes
Centro de Investigación en el Comportamiento de la Salud
Departamento de Psicología (0274)
Blacksburg, VA 24061

¡Muchas Gracias!

Appendix X. Chapter 5 Institutional Review Board approval letter
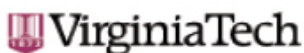
VirginiaTech

Office of Research Compliance
Institutional Review Board
North End Center, Suite 4120, Virginia Tech
300 Turner Street NW
Blacksburg, Virginia 24061
540/231-4606 Fax 540/231-0959
email irb@vt.edu
website http://www.irb.vt.edu

MEMORANDUM

DATE: January 28, 2015

TO: Dr. Kathryn Hosig, Ivette G Valenzuela

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires April 25, 2018)

PROTOCOL TITLE: Hispanic Balanced Living with Diabetes Focus Group

IRB NUMBER: 15-076

Effective January 28, 2015, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

http://www.irb.vt.edu/pages/responsibilities.htm

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Expedited, under 45 CFR 46.110 category(ies) 6,7**
Protocol Approval Date: **January 28, 2015**
Protocol Expiration Date: **January 27, 2016**
Continuing Review Due Date*: **January 13, 2016**
*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

————— *Invent the Future* —————

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
An equal opportunity, affirmative action institution

Appendix Y. Consent form (English)

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
**Informed Consent for Participants
in Research Projects Involving Human Subjects**

Title of Project: **A1c and Lipid Panel Outcomes for Hispanic Adults with pre-diabetes and type 2 diabetes in a Community-based Lifestyle Intervention Program.**

Investigator(s): **Kathy Hosig, PhD, MPH, RD** **khosig@vt.edu/ (540) 231-6637**
Name   E-mail / Phone number

Ivette Valenzuela, MPH **ivettev@vt.edu / (540) 231-6637**
Name   E-mail / Phone number

I. Purpose of this Research Project
Focus groups have three purposes: 1) learn about healthcare barriers faced by the Hispanic community in Virginia; 2) investigate the feasibility of train a community member to become a promotora; and 3) receive feedback about Hispanic Balanced Living from participants.

II. Procedures
Participation in this project is completely voluntary. Focus group will be audio-taped. If you agree to participate, your commitment to this project will involve the completion of one focus group discussion. The focus group session should take between1 and 1-1/2 hours and will be done at Francis of Assisi and/or Sacred Heart Catholic Churches. The date and time will be the most convenient to the group.

III. Risks
Participation in this study poses minimal risk. Questions asked during the focus group might be a little uncomfortable. You are free to not answer the questions. All information will be confidential. Others in the group will be told that they should not share things you say with people outside the group. All participants will be expected and encouraged to show respect for others and their comments.

IV. Benefits
Participation in the group discussion about diabetes education and access to care may motivate participants to take better care of their diabetes or get more medical care. Collecting information about perceived problems that people have in taking care of their diabetes may help find solutions to those problems. For example, a promotora might help members of the community find and receive healthcare more easily. The information we get from participants will also help to make improvements to HBLD. This information will also help to identify reasons that the Hispanic community is at risk for poor health.

V. Extent of Anonymity and Confidentiality

All of the information we collect from you will be confidential. The only place we will have your name is on this consent form. Participants will be given letter codes (A, B, C, D, etc.) to identify participants without using names in our notes. Each participant will be given a different study code to use on study forms. This code will be noted on this consent form. The consent form will be the only document that links your name with your study code. The consent form and a list of names and code numbers will be kept in a locked cabinet.

The Virginia Tech (VT) Institutional Review Board (IRB) may view the study's data to make sure we are protecting your rights. The IRB is responsible for the oversight of the protection of human subjects involved in research.

VI. Compensation

If you agree to participate, you will receive $10 cash. Additionally, a light meal and beverage will be provided at the focus group session.

VII. Freedom to Withdraw

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free not to answer any questions that you choose or respond to what is being asked of you without penalty.

Please note that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

Should you withdraw or otherwise discontinue participation, you will be compensated for the portion of the project completed in accordance with the Compensation section of this document.

VIII. Subject's Consent

I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

_____ Date_____
Subject signature

_____
Subject printed name

IX. Questions or Concerns

Should you have any questions about this study, you may contact one of the research investigators whose contact information is included at the beginning of this document.

Should you have any questions or concerns about the study's conduct or your rights as a research subject, or need to report a research-related injury or event, you may contact the VT IRB Chair, Dr. David M. Moore at moored@vt.edu or (540) 231-4991.

(Note: each subject must be provided a copy of this form. In addition, the IRB office may stamp its approval on the consent document(s) you submit and return the stamped version to you for use in consenting subjects; therefore, ensure each consent document you submit is ready to be read and signed by subjects.)

Appendix Z. Consent form (Spanish)

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Consentimiento Informando para Participantes en Proyecto de Investigación que envuelven Sujetos Humanos

Nombre del Proyecto: Resultados de A1c y lípidos en Adultos Hispanos con pre-diabetes y diabetes tipo 2 en un Programa de Intervención Comunitaria basada en el Estilo de vida.

Investigadoras: **Kathy Hosig, PhD, MPH, RD** **khosig@vt.edu/ (540) 231-6637**
Nombre E-mail / Número de Teléfono

Ivette Valenzuela, MPH **ivettev@vt.edu / (540) 231-6637**
Nombre E-mail / Número de Teléfono

I.   Descripción del estudio:
Los grupos de discusión tienen tres propósitos: 1) aprender acerca de las barreras de salud que enfrenta la comunidad hispana en Virginia; 2) investigar la factibilidad de entrenar un miembro de la comunidad para convertirse en promotora; y 3) recibir comentarios de los participantes sobre Vida Balanceada con Diabetes (HBLD).

II.   Procedimientos
La participación en este proyecto es completamente voluntaria. Los grupos de discusión serán audios grabados. Si está de acuerdo en participar, su compromiso con este proyecto implicará la ser parte de un grupo de discusión. La sesión de grupo tomara entre 1 y 1-1 / 2 horas, y se llevara a cabo en las Iglesias Francisco de Asís y / o Sagrado Corazón. La fecha y la hora será la más conveniente para el grupo.

III.   Riesgos
La participación en este estudio presenta un riesgo mínimo. Las preguntas formuladas durante el grupo de discusión podrían ser un poco incómodo. Usted es libre de no responder a las preguntas. Toda la información será confidencial. A los otros miembros del grupo se les dirá que no deben compartir cosas que dices con personas fuera del grupo. Se espera y se animara a todos los participantes a a mostrar respeto por los demás y sus comentarios.

IV.   Beneficios
La participación en el grupo de discusión sobre la educación en diabetes y el acceso a la atención puede motivar a los participantes a cuidar mejor de su diabetes o conseguir más atención médica. La recopilación de información sobre los problemas percibidos que tienen las personas en el cuidado de su diabetes puede ayudar a encontrar soluciones a esos problemas. Por ejemplo, una promotora podría ayudar a los miembros de la comunidad a encontrar y recibir atención médica con mayor facilidad. La información que recibimos de los participantes también ayudará a hacer mejoras en HBLD. Esta información también ayudará a identificar las razones por las que la

comunidad hispana está en riesgo de problemas de salud.

V. Extensión de anonimato y confidencialidad

Toda la información que obtenemos de usted será anónima. El único lugar en que tendremos su nombre es en el formulario de consentimiento. Los participantes recibirán códigos de letras (A, B, C, D, etc.) para identificar a los participantes sin usar nombres en nuestras notas. Cada participante recibirá un código de estudio diferente a utilizar en los formularios de estudio. Este código será anotado en este formulario de consentimiento. El formulario de consentimiento será el único documento que vincula su nombre con su código de estudio. El formulario de consentimiento y una lista de nombres y números de código se mantendrán en un armario cerrado con llave

La Junta de Revisión Institucional (IRB) de Virginia Tech (VT) puede ver los datos del estudio para fines de auditoría. El IRB es responsable de la supervisión de la protección de los sujetos humanos que participan en la investigación.

VI. Compensación

Si está de acuerdo en participar, usted recibirá $ 10 en efectivo. Además, se proporcionará una comida ligera y bebida en la sesión de grupo de discusión.

VII. Libertad para retirarse

Es importante que usted sepa que usted es libre de retirarse de este estudio en cualquier momento sin penalización. Usted es libre de no responder a cualquier pregunta que usted elija o responder a lo que se pide sin penalización.
Tenga en cuenta que puede haber circunstancias en las que el investigador puede determinar que un sujeto no debe continuar como sujeto.
En caso de retirar o de lo contrario dejar de participar, usted será compensado por la parte del proyecto completado de acuerdo con la sección de Compensación de este documento.

VIII. Consentimiento del Sujeto

He leído el formulario de consentimiento y condiciones de este proyecto. Todas mis preguntas han sido contestadas. Por la presente reconozco lo anterior y doy mi consentimiento voluntario:

_____   Fecha: _____
Firma del sujeto

_____
Nombre escrito del sujeto

IX. Preguntas o Preocupaciones

Si tiene alguna pregunta acerca de este estudio, puede contactar a uno de los investigadores cuya información de contacto se incluye al principio de este documento.

Si tiene alguna pregunta o preocupaciones sobre la forma que fue conducida este estudio o sus derechos como sujeto de investigación, o necesita reportar un evento o lesiones relacionadas con la investigación, puede comunicarse con el presidente de VT IRB, Dr. David M. Moore at moored@vt.edu o (540) 231-4991.

(Nota: a cada sujeto se le deberá de proporcionar una copia de este formulario. Además, la oficina IRB puede estampar su aprobación en los documentos de consentimiento que presente y devolverla la versión estampada para su uso en sujetos adultos; por lo tanto, asegúrese que cada documento de consentimiento que se entregue esté listo para ser leído y firmado por temas.)

Appendix AA. Recruitment material (English)

<div style="border:2px solid black; padding:1em;">

PARTICIPANTS NEEDED!
Please help us to learn about your barriers to getting healthcare
And let us know how HBLD can be improved.

Virginia Tech has partnered with Francis of Assisi Catholic Church to conduct a focus group to learn more about healthcare barriers faced by the Hispanic community in Virginia and to learn about how to improve Hispanic Balanced Living with Diabetes (HBLD) and offer it to more people. This information will help churches like ours to:

- Learn possible ways to help Hispanic community members get health care.
- Improve HBLD and offer it to more community groups.

We are looking for 12-16 participants to help with this project! If you are interested here's what you need to know

What's the purpose of this project again?

- To learn about things that make getting healthcare difficult for the Hispanic community in Virginia.
- Participants will provide feedback about their experience in the HBLD program.

How do I know if I can participate?

- Did you participate in HBLD at Francis of Assisi?
  If your answer is YES, you can participate

If I'm interested, what do I have to do?

- Sign a consent form.
- Participate in a group discussion that will last about 1-1/2 hour.
- Focus groups will be audiotaped.
- All information is confidential.

Will I get compensated for my time?

- Yes, a light meal will be provided at each session and each participant will receive a $10 gift card.

What will the focus group be about?

- A moderator will ask questions about and the answers will be audio-taped:
  - Things that make getting healthcare difficult for the Hispanic community in Virginia
  - How to improve HBLD

When the focus will take place and where will it be held?

- The focus group is planned for some time in February
- The focus group will be held at Francis of Assisi

If you would like to participate or have further questions please contact Ivette Valenzuela @ 781-330-6734

</div>

Appendix BB. Recruitment material (Spanish)

¡SE NECESITAN PARTICIPANTES!
Por favor, Ayúdanos a aprender acerca de sus barreras de acceso a la atención médica
Y déjenos saber cómo HBLD puede ser mejorado.

Virginia Tech se ha asociado con la Iglesia Católica del Sagrado Corazón para realizar un grupo de enfoque para aprender más acerca de las barreras de salud que enfrenta la comunidad hispana en Virginia y para aprender acerca de cómo mejorar Vida Balanceada con Diabetes (HBLD) y ofrecerlo a más personas. Esta información ayudará a las iglesias como la nuestra a:

- Aprender posibles maneras de ayudar a los miembros de la comunidad hispana a obtener atención médica.
- • Mejorar HBLD y ofrecerlo a más grupos de la comunidad.

¡Estamos en busca de 12-16 participantes para ayudar con este proyecto! Si usted está interesado esto es lo que usted necesita saber

¿Cuál es el propósito de este proyecto?

• Aprender acerca de las cosas que dificultan obtener atención médica para la comunidad hispana en Virginia.
• Los participantes proporcionarán comentarios sobre su experiencia en el programa HBLD

¿Cómo sé si puedo participar?

¿Participó en HBLD en la Iglesia Sagrado Corazón?

Si su respuesta es SI, usted puede participar

Si estoy interesado, ¿qué tengo que hacer?

• Firme un formulario de consentimiento.
• Participe en una discusión de grupo que va a durar alrededor de 1-1 / 2 hora.
• Se grabaran los grupos de discusión.
• Toda la información es confidencial.

¿Me compensaran por mi tiempo?

- Sí, una comida ligera será proporcionado en cada sesión y cada participante recibirá una tarjeta de regalo de $ 10.

¿En qué consistirá la discusión de grupo?

- Un moderador hará preguntas que serán grabadas en audio acerca de:
  - Cosas que dificultan conseguir atención médica para la comunidad hispana en Virginia
  - Cómo mejorar HBLD

¿Cuándo y a dónde el grupo de discusión se llevará a cabo?

- El grupo de discusión está planeada para algún momento de febrero
- El grupo de discusión tendrá lugar en la iglesia Sagrado Corazón

Si a usted le gustaría participar o tiene más preguntas por favor póngase en contacto con Ivette Valenzuela @ 781-330-6734

Appendix CC. Focus Group Interview Guide (English)

<u>Focus Group Interview Guide</u>

[Moderator]: This is a research project of Virginia Tech. Results will be used in a graduate student research report and may be published in a research magazine. No names will be used in these reports. This discussion has three purposes: 1) learn about healthcare barriers faced by the Hispanic community in Virginia; 2) find out whether participants believe it is a good idea to recruit and train members of the Hispanic community to be promotoras; and 3) receive feedback about the Hispanic Balanced Living program from participants. There are no right or wrong answers and any information you provide will be helpful.

Access to healthcare:

1. Do you have a doctor or other healthcare professional that you go to for checkups?
      a. If yes, how did you find this person?
      b. If no, what are some reasons that you do not go for checkups?
2. What do you do when you are sick?
3. What things make it difficult for you to get help when you need to see a doctor or have questions about your health or your family's health?
4. What could make it easier for you to get help when you need to see a doctor or have questions about your health or your family's health?

Promotora:
Moderator will explain the possible role of promotora as liaison among patients and healthcare system.

A promotora de salud is a person from the community who has been trained to educate, motivate, and support the members of her or his community to be healthier by promoting healthy lifestyles. A promotora can be also be trained to help his or her community members to find places to go for health care and to make it easier to get health care.

1. Do you think a trained promotora will help people in the Hispanic community be able to find medical help that they need?
2. Would you ask a Hispanic community member trained as a promotora for help in finding medical care and nutrition information?
      a. Do you think other people you know would like to talk with promotoras?
      b. Why or why not?
3. Do you know Hispanic people in your community who might be good promotoras and might be willing to serve as promotoras?
      a. What types of people would be good at being promotoras?
      b. What do you think would be needed to get people to agree to be trained as promotoras?
      c. What are some reasons you think it might be difficult to find people to be promotoras?

Hispanic Balanced Living with Diabetes

1. What did you like about the program?
2. What you did not like about the program?

3. How can the program be improved?
4. If the program is delivered in a place other than church, would you still participate?
5. Was having a Spanish speaking educator helpful?
6. What do you think about having an English-speaking educator if there is someone at the class to translate into Spanish?
7. Have you been to other diabetes classes or education?
   a. Why or why not?
      i. Would having to have health insurance keep you from going for diabetes education?
      ii. Would having to pay for diabetes education keep you from going for diabetes education?

General Nutrition Education

1. Where do you get information about eating healthy?
   a. Would you and your friends be willing to come to free classes about eating healthy?
2. Please tell us about places people can go in your community if they do not have enough food for their family to eat
   a. Do people know about these places?
   b. How do they find out about these places?
   c. Are people comfortable asking for help to get enough food?

[Moderator]: Thank you for taking the time to chat with me today. Do you have any questions? Is there anything else you'd like to add before we finish up? Ok, great!

Appendix DD. Focus Group Interview Guide (Spanish)

1

Guía de Entrevista para Grupo de Discusión

[Moderador]: Se trata de un proyecto de investigación de Virginia Tech. Los resultados serán utilizados en un informe de investigación de estudiante de posgrado y podrán ser publicados en una revista de investigación. Ningún nombre se utilizará en estos informes. Esta discusión tiene tres propósitos: 1) aprender acerca de las barreras de salud que enfrenta la comunidad hispana en Virginia; 2) averiguar si los participantes creen que es una buena idea reclutar y entrenar a miembros de la comunidad hispana para promotoras; y 3) recibir comentarios sobre el programa Vida Balanceada con Diabetes No hay respuestas correctas o incorrectas y cualquier información que usted proporcione será útil.

Acceso a atención médica:

1. ¿Tiene un médico u otro profesional de la salud a donde usted vaya a sus chequeos médicos regulares?
    a. En caso afirmativo, ¿cómo encontró a esta persona?
    b. Si no, ¿cuáles son algunas de las razones para no ir a sus chequeos médicos regulares?
2. ¿Qué hace cuando está enfermo?
3. ¿Qué cosas hacen que sea difícil para que usted pueda obtener ayuda cuando usted necesita ver a un médico o tiene preguntas sobre su salud o la de su familia?
4. ¿Qué podría hacer más fácil para usted para obtener ayuda cuando necesita ver a un médico o tiene preguntas sobre su salud o la de su familia??

Promotora:
El moderador explicará el posible papel de promotora como enlace entre los pacientes y el sistema de atención médica.

Una promotora de salud es una persona de la comunidad quien ha sido entrenada para educar, motivar y apoyar a los miembros de su comunidad a ser más saludables mediante la promoción de estilos de vida saludables. Una promotora también puede ser entrenada para ayudar a los miembros de su comunidad a encontrar lugares para ir para el cuidado de la salud y para que sea más fácil conseguir la atención de salud.

1. ¿Cree usted que una promotora entrenada ayudaría a las personas en la comunidad hispana para ser capaz de encontrar la ayuda médica que necesitan?
2. ¿Le preguntaría a un miembro de la comunidad se formó como una promotora para la ayuda en la búsqueda de información de atención médica y la nutrición?
    a. ¿Cree usted que la gente que usted conoce quisiera hablar con las promotoras?
    b. ¿Por qué o por qué no?
3. ¿Conoces a hispanos en su comunidad que podrían ser buenos (as) promotoras y podrían estar dispuestos a servir como promotoras?
    a. ¿Qué tipo de gente sería bueno en ser promotoras?
    b. ¿Qué piensa usted que sería necesario para que la gente se ponga de acuerdo para ser entrenados como promotoras?
    c. ¿Cuáles son algunas razones por las que creo que puede ser difícil encontrar personas a ser promotoras?

Vida Balanceada con Diabetes

1. ¿Qué le gustó de este programa?
2. ¿Qué no le gustó del programa?
3. ¿Cómo se puede mejorar el programa?
4. Si el programa se imparte en un lugar distinto de la iglesia, ¿aún participaría??
5. ¿Fue útil tener un educador que habla español?
6. ¿Qué piensa acerca de tener un educador que hablan inglés, si hay alguien en la clase que traduciría al español?
7. ¿Ha estado en otras clases de diabetes o la educación de diabetes?
   a. ¿Por qué o por qué no?
      i. ¿Si tener que tener seguro de salud que dejar de ir para la educación de la diabetes?
      ii. ¿Tener que pagar por la educación en diabetes hubiera hecho que usted no recibiera la educación en diabetes?

Educación General de Nutrición

1. ¿De dónde sacas la información sobre alimentación saludable?
   a. ¿Usted y sus amigos estarán dispuestos a venir a clases gratuitas acerca de cómo comer sano?
2. Por favor díganos acerca de los lugares que la gente puede ir en su comunidad si no tienen suficiente comida para su familia para que su familia coma
   a. ¿Sabe la gente acerca de estos lugares?
   b. ¿Cómo se enteran de estos lugares?
   c. ¿Se siente la gente cómoda pidiendo ayuda para conseguir suficiente alimento?

[Moderador]: Gracias por tomarse el tiempo para charlar conmigo hoy. ¿Tiene alguna pregunta? ¿Hay algo más que le gustaría añadir antes que terminemos? Ok, genial!