



AN ABSTRACT OF THE DISSERTATION OF

Beverly Baird White for the degree of Doctor of Philosophy in Nutrition and Food Management presented on May 3, 2006.

Title: Hispanic Family Diabetes Project: A Pilot Intervention Study.

Abstract approved:

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Melinda M. Manore

Changes in lifestyle over the last century have resulted in a dramatic increase in the incidence of diabetes in the United States (U.S.). Mexican-Americans, the largest Hispanic/Latino subgroup in the U.S., are 1.7x's as likely to have diabetes as non-Hispanic Whites. Culturally appropriate approaches for treating diabetes in minority groups have rarely been investigated and traditional interventions have been ineffective.

The purpose of this study was to test whether a culturally appropriate (i.e., language, food, and beliefs) diabetes intervention pilot program that focused on nutrition, physical activity (PA), and self-care for Hispanic participants with diabetes, could improve lifestyle/medical diabetic risk factors. Outcome variables collected pre/post-intervention were servings/day of fruits, vegetables, whole grains; intake of saturated fat; PA (minutes/week); blood glucose, insulin, glycosylated hemoglobin, total cholesterol, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, triglycerides, and insulin resistance.

This study was unique as the intervention was completed in both urban/rural settings, in a manageable time frame, with outcome variables that included change in diet/exercise, blood lipids, and insulin resistance. The education program (6-10 weeks; 20-25 hours) was offered in Multnomah (MC) and Hood River (HRC) counties using bilingual/bicultural community health workers. Counties selected 1 of 2 ways to implement the program. Participants were encouraged to bring a friend/family member for support.

The intervention significantly increased ( $p < 0.05$ ) intakes of whole grains in both counties, while saturated fat and fruit intake significantly decreased ( $p < 0.05$ ) in MC. No significant changes occurred in PA or blood assessment variables; however, participants in HRC reported a 10% increase in PA (87 to 96 minutes/week) compared to 47% in MC (51 to 75 minutes/week). The 2 counties were different in eating habits, PA, and biomarkers. At baseline, participants in MC ate more vegetables, and those in HRC ate more whole grains, had lower insulin levels, and higher HDL cholesterol levels ( $p < 0.05$ ).

The intervention resulted in modest changes in some outcome variables; however, a longer intervention appears to be necessary to significantly improve lifestyle behaviors and biomarkers for the treatment of diabetes. The participants rated the program highly due to the culturally appropriate approach used.

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Hispanic Family Diabetes Project:  
A Pilot Intervention Study

by  
Beverly Baird White

A DISSERTATION

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degree of

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Doctor of Philosophy dissertation of Beverly Baird White presented on May 3, 2006.

APPROVED:

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Major Professor, representing Nutrition and Food Management

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Chair of the Department of Nutrition and Exercise Sciences

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Dean of the Graduate School

I understand that my dissertation will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my dissertation to any reader upon request.

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Beverly Baird White, Author

## ACKNOWLEDGMENTS

When I first started out on this educational endeavor, Dr. Don Prickel told me I was going to be working toward a degree of perseverance. Five and a half years later that is indeed what has been accomplished. There are so many individuals and organizations that assisted in my journey and they deserve special recognition at this time.

Without financial support, the past 5 ½ years would have only been a vision not a reality for me. I was extremely fortunate to receive scholarship assistance from the American Dietetic Association, the Consulting Dietitians in Health Care Facilities Dietetic Practice Group, and the College of Health and Human Sciences at Oregon State University. In addition, this study would not have been possible without the funding that was provided by the State of Oregon, Department of Human Services – Health Services, Health Promotion and Chronic Disease Prevention Program, as well as the Department of Health and Human Services, Office of Women’s Health, Region X.

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County Health Department, and in Hood River County, Janet Hamada, Program Manager with Nuestra Comunidad Sana and Margie Dogotch, RN, Salud Program Manager at La Clinica del Cariño. All 3 of these individuals spearheaded and organized the data gathering process and implemented the educational programs in their respective counties. Without their leadership, guidance, and assistance, this pilot project would not have run as smoothly as it did.

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offering your insight on adult education. Thank you Dr. Carolyn Raab for guiding me in the early years when I was indecisive about what I was doing and where I was going. Above all, I would like to express my sincere appreciation to Dr. Don Prickel and Dr. Melinda Manore. When I first came on campus, Dr. Don Prickel showed a genuine interest regarding my reentry back to college that was so captivating it made me excited and ready to leap into areas that were out of my comfort zone. Even though he has not always been physically in my presence, he has been a beacon guiding me along, and has been paramount in my success due to his belief in me. Last, but certainly not least, I would like to extend my deepest gratitude to Dr. Melinda Manore for her tireless energy, guidance, wisdom, and her delightful sense of humor. She pushed me further than I think anyone has ever pushed me before. I thank her for believing in me, her constant support, and being there when needed.

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Dedicated to.....

My mom ~

You provide a continuing source of encouragement and support.  
Never have you tried to discourage me from my hopes  
and dreams. Thank you for the belief you have  
in me. I love you very much.

My dad ~

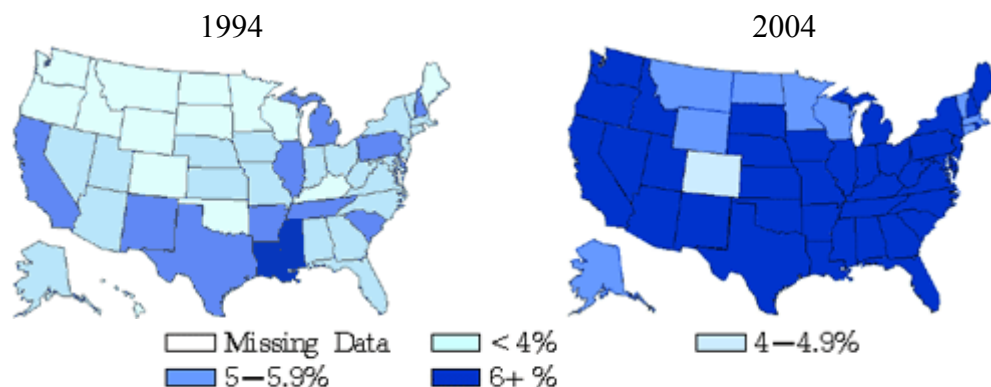
I miss your patient, well-thought advice, that helped guide me over  
the years. You instilled in me attributes such as independence,  
how to be resourceful, and to aim high. I love and miss  
you very much, may you rest in peace.

# Hispanic Family Diabetes Project: A Pilot Intervention Study

## CHAPTER 1 - INTRODUCTION

Diabetes mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin action and/or insulin production. Type 2 diabetes is the most prevalent form of diabetes and results from a combination of insulin resistance (an inability of insulin to carry out its function appropriately) and insulin deficiency (an inability of the beta cells to produce enough insulin). Some 90 to 95% of persons with diabetes suffer from this type of diabetes, and approximately 80% of them are obese or have a history of obesity at the time of diagnosis (Mahan and Escott-Stump, 2000).

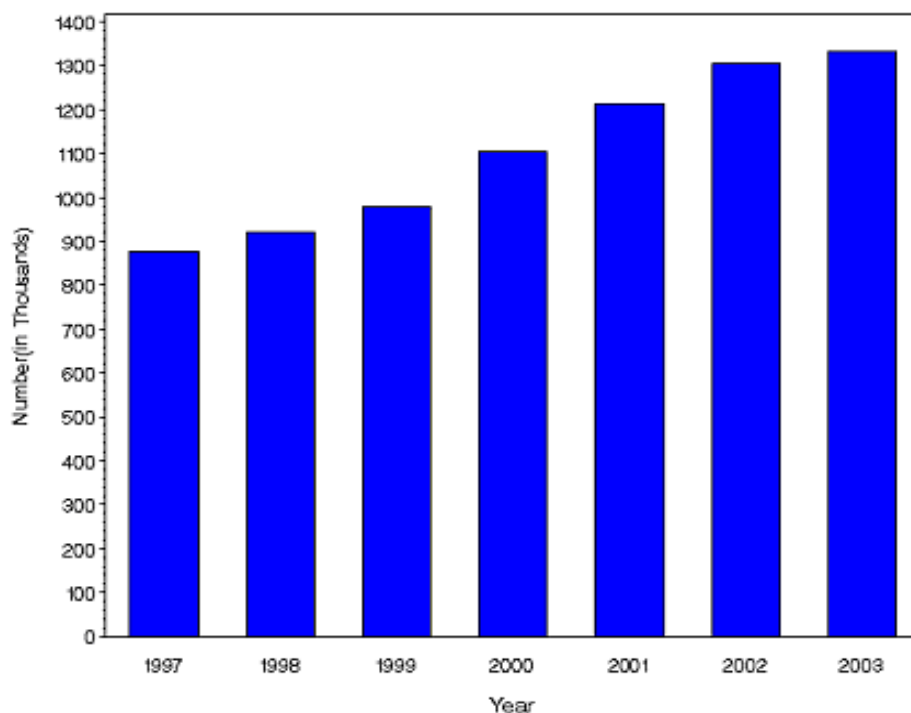
The total prevalence of diabetes in the United States (U.S.) for all ages as of 2005 was 20.8 million people, 7% of the population (CDC, 2005). The occurrence of diabetes, especially type 2 diabetes, as well as associated complications, is increasing in the United States (CDC, 2005), which is captured in Figure 1.1 below. From 1997



Source: <http://www.cdc.gov/diabetes/statistics/prev/state/fPrev1994and2004.htm>

**Figure 1.1 Age-adjusted prevalence of diagnosed diabetes per 100 adult population, by state, United States, 1994 and 2004**

through 2003, the number of new cases of diagnosed diabetes among adults increased by 52% (Figure 1.2).



Source: [www.cdc.gov/diabetes/statistics/incidence/fig1.htm](http://www.cdc.gov/diabetes/statistics/incidence/fig1.htm)

**Figure 1.2 Annual number (in thousands) of new cases of diagnosed diabetes among adults aged 18–79 years, United States, 1997–2003**

Type 2 diabetes is on the rise for a variety of reasons. The most pressing reasons include an increase in type 2 diabetes in obese children and adolescents and an increase in risk factors associated with the development of diabetes such as obesity and lack of physical activity in adults (DHHS, 2000).

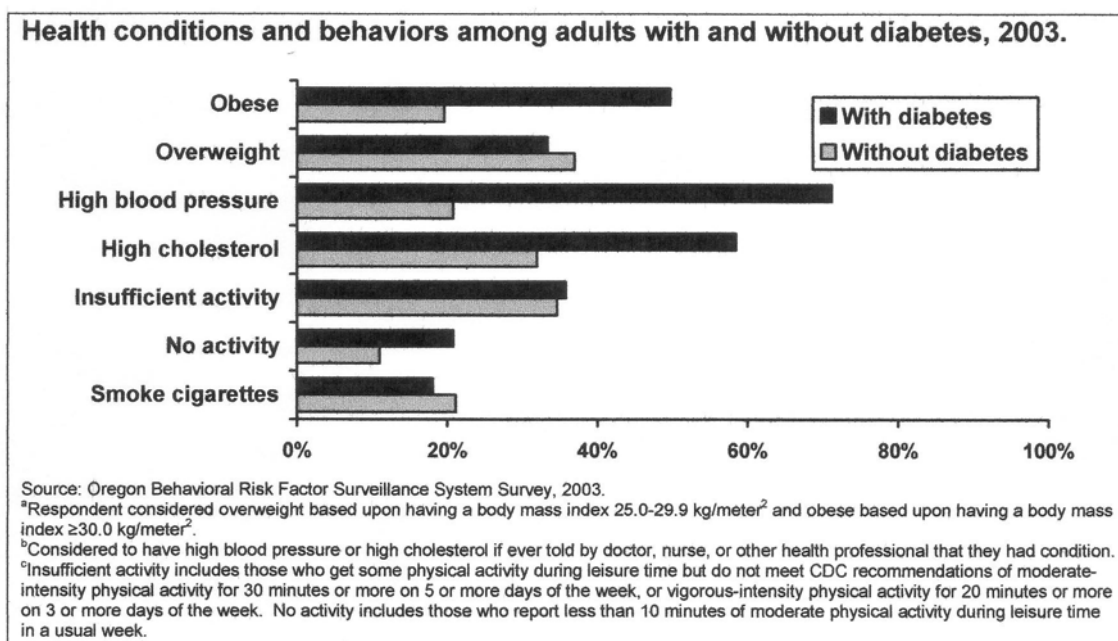
Diabetes disproportionately affects Hispanics in the United States. According to the Centers for Disease Control and Prevention (CDC), after adjusting for population age differences, Mexican-Americans, the largest Hispanic/Latino subgroup, are 1.7 times as likely to have diabetes as non-Hispanic Whites (CDC, 2005). If the prevalence of

diabetes among Mexican-Americans was applied to the total Hispanic/Latino population, about 9.5% Hispanic/Latino Americans aged 20 years or older would have diabetes (CDC, 2005). This increased susceptibility is probably attributable to both genetic factors and to an increased prevalence of risk factors, such as obesity (Mahan and Escott-Stump, 2000).

In Oregon, as in the rest of the U.S., diabetes is a major health problem (DHS, 2005). The percentage of adult Oregonians with diagnosed diabetes rose from 4% in 1993 to 6% in 2003, this is an increase of over 30% in the last 10 years, after adjusting for age (DHS, 2005 Report Card). Currently, an estimated 163,700 adult Oregonians have been diagnosed with diabetes and another 66,900 likely have the disease but don't know it (DHS, 2005 Report Card).

Diabetes increases the risk of morbidity for those who have the disease. Many people with diabetes are at risk for complications for other health problems and chronic diseases, which may include heart disease and stroke, high blood pressure, blindness, kidney disease, nervous system diseases, amputations, and dental disease (CDC, 2005). Oregonians with diabetes reported a higher average number of days in the preceding month where poor physical or mental health kept them from doing their usual activities such as self-care, work, or recreation compared to those without diabetes (DHS, 2005 Report Card). Figure 1.3 shows the prevalence of health conditions and behaviors among adult Oregonians with and without diabetes (DHS, 2005 Report Card).

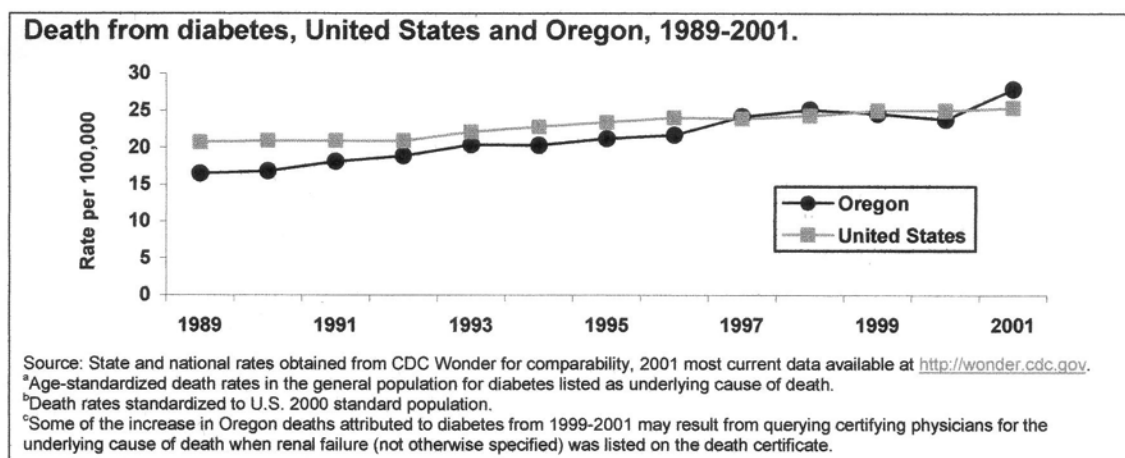
Diabetes also increases the risk for mortality. In 2002, diabetes was the seventh leading cause of death in Oregon (DHS, 2005 Report Card); however, diabetes is likely to



**Figure 1.3 Health conditions and behaviors among adult Oregonians with and without diabetes, 2003**

be underreported as a cause of death (CDC, 2005). Approximately 35 to 40% of decedents with diabetes have diabetes listed anywhere on the death certificate and only about 10 to 15% have it listed as the underlying cause of death (CDC, 2005). Overall, the risk for death among individuals with diabetes is about twice that of individuals without diabetes of similar age (CDC, 2005). The death rate from diabetes in the general population has steadily increased since 1989, as indicated in Figure 1.4.

The Hispanic/Latino population is Oregon's largest growing ethnic group. According to the 2000 census data, they now represent 9% of the state's population. The majority of Hispanics in Oregon have come from Mexico (ODPCP, 2003). More and more migrant or seasonal workers have become year-round residents in areas of the state where agriculture predominates (ODPCP, 2003). Oregon's Hispanic population is very young, 43% are 19 years old and younger, and another 23% are between the ages of 20



**Figure 1.4 Death from diabetes, United States and Oregon, 1989-2001**

and 29 (ODPCP, 2003). Many of them have incomes below the federal poverty level, 25% compared to 10% of all Oregonians, and more of them lack health insurance (24.5%) than Oregon's non-Hispanic population (12%) (ODPCP, 2003).

The Hispanic/Latino population in Oregon are disproportionately affected by diabetes mortality. From 2000-2002 the age-standardized death rate for diabetes was 26.8 per 100,000 persons for non-Hispanics or Latinos and 32.1 per 100,000 for Hispanics or Latinos (DHS, 2005 Report Card). The toll of diabetes on the health status of people in the U.S. is expected to worsen before it improves, especially in vulnerable, high-risk populations such as Hispanics. One potential reason for the greater burden of diabetes within certain racial and ethnic groups is inadequate access to proper health care. This places an enormous financial burden on families and the health care system.

There appears to be a glaring gap in the literature examining the impact of diabetes education research conducted with minority groups whom bear a disproportionate burden of type 2 diabetes, Native Americans, Mexican-Americans, and



African Americans, in particular (Brown and Hanis, 1999). Culturally appropriate approaches taking into consideration language, food, cultural beliefs, and method of educational delivery designed for minority groups have rarely been investigated, and traditional interventions have been ineffective (Brown and Hanis, 1999). Past strategies designed for middle-class, non-Hispanic Whites ignored important cultural attributes and values of individuals from Hispanic heritage: traditional male and female gender roles; a strong interdependence with family members; the value of mutual respect and conformity, particularly with strangers perceived to have authority; and belief of older, less acculturated Mexican-Americans that illness results from wrong doing (Brown and Hanis, 1999). According to Jezewski and Poss (2002) one belief system that shapes the way Hispanics think about diabetes is the folk belief system which attributes the cause of diabetes to experiencing strong emotions (i.e., fright, anger, sadness or depression). In addition, Hispanics are more likely than non-Hispanic Whites to seek care from traditional healers, take dietary supplements, or use home remedies; i.e., herbal therapies such as prickly pear cactus (nopal) and aloe vera (sabila) (Coronado et al, 2004).

Table 1.1 summarizes 4 of the primary diabetes intervention published research focused on nutrition, exercise, and self-management (Elshaw et al, 1994; Brown and Hanis, 1999; Banister et al, 2004; Lemon et al, 2004). In 3 of the 4 studies (Elshaw et al, 1994; Brown and Hanis, 1999; Banister et al, 2004) the participants were Hispanic and the program was delivered in the preferred language, either Spanish or English. The length of diabetes education interventions described in all 4 of the studies reviewed ranged from 8 weeks to 12 months; however, even though the Banister study (2004) had a 12 month intervention there was only  $6.5 \pm 3.0$  hours of contact/education time with the

**Table 1.1 Summary of diabetes intervention published research**

Study	Participants	Intervention	Length	Outcome Variables	Sig Diff ( $p < 0.05$ )
Elshaw et al. 1994	n=78, T 74% completion  n=74, C 62% completion  (elderly Mexican- Americans w/type 2 diabetes)	T=Nutrition  C=no intervention	T=weekly education sessions for 8 weeks  (2h/session)	Body weight loss	T & C (males)  C=females
				Decreased energy intake	C=males
				Decreased cholesterol intake	C=females
Brown and Hanis 1999	n=125, T 50% completion  n=122, C  (n=Mexican- Americans w/type 2 diabetes & support person)	T=Nutrition, exercise, & self-mgmt C=no intervention	T=12 mo  (26 sessions over 1 y, 2h/ session)	HgbA1c (%)	no
				Fasting blood glucose (mg/dL)	yes at 6 mo (signif. level not specified)
Banister et al. 2004	n=70, T  No C  (Mainly Hispanics or African Americans w/type 2 diabetes)	T=Diabetes self- mgmt  No C	12 mo  -a 4 h group class offered monthly -followed by $\geq 1$ individual consultation w/RD -no support meetings  (mean hours of attending all 3= 6.5 +/- 3.0)	HgbA1c (%)	yes
				Decrease medication use	yes
				Body mass index (BMI)	no
Lemon et al. 2004	n=244, T (184 finished)  No C  (non-Hispanic adults w/type 2 diabetes)	T=Nutrition + counseled by 59 RDs in outpatient and inpatient clinic settings  No C	6 mo  RDs spent an avg of 111 +/- 55 mins w/each subject & met w/subjects an avg of 2.1 +/- 1.0 times	HgbA1c (%) Fasting plasma glucose (mmol/L) 5-year CHD risk (%) Diet/lifestyle questionnaire Exercise assessment	yes yes  yes yes  yes

T=Treatment; C=Control; RD=Registered Dietitian; HgbA1c=Glycosylated hemoglobin

participants.

For 2 of the 4 studies nutrition education was the main intervention (Elshaw et al, 1994; Lemon et al, 2004) while the Banister study (2004) focused on self-management. However, the study that had the most comprehensive education program, was completed by Brown and Hanis (1999). This program included nutrition, exercise, self-management, and the inclusion of a support person. One of the primary outcome variables used in 3 of the 4 studies was glycosylated hemoglobin (HgbA1c) (Brown and Hanis, 1999; Banister et al, 2004; Lemon et al, 2004), but only 2 reported significant improvements post-intervention (Banister et al, 2004; Lemon et al, 2004). Even though the study by Lemon and colleagues (2004) did not use Hispanic participants they measured additional outcome variables to assess change in coronary heart disease (CHD) risk, self-management behaviors, diet, and exercise.

Of the 4 studies outlined in Table 1.1, the Brown and Hanis study (1999) was most unique in a number of ways. First, it focused on targeting the Hispanic person with diabetes and a family member/support person for improving health behaviors. Second, it was designed with an emphasis on culturally acceptable lifestyle recommendations. Third, the intervention was taught in the preferred language, usually a blend of Spanish and English. Fourth, it focused on reducing blood glucose levels rather than on weight reduction. One major limitation of this study was that it lasted 1 year and; thus, attendance was only 50% post-intervention and contact with the participants was limited to ~ 2 times/month. An additional limitation is the researchers did not look at the impact of social support on outcome variables.

To date, no study has combined nutrition, exercise, self-management, and the

inclusion of a support person in an educational intervention program delivered in Spanish for Hispanics with diabetes living in both rural and urban areas in a manageable time frame, with outcome variables addressing nutrition, exercise, self-management, and social support. Therefore, the purpose of this study is to test whether a culturally appropriate diabetes education intervention program that focuses on nutrition, physical activity, and self-care management for Hispanic participants with diabetes and their support person(s), will significantly improve both lifestyle and medical diabetic risk factors for diet, physical activity, and biochemical measurements. All participants with diabetes will be assessed before (pre) and after (post) the intervention program.

## RESEARCH QUESTIONS AND HYPOTHESES

### Primary Research Questions

1. Do participants self-report eating more servings/day of whole grains, fruits, and vegetables after (post) the intervention program than before (pre)?

Hypothesis: Participants will self-report consuming more servings/day of whole grains, fruits, and vegetables after the intervention program than before.

Servings/day	Pre-test*	Post-test*
Whole grains	√	√
Fruits	√	√
Vegetables	√	√

\*Measured by servings/day using the Spanish SWAN (Study of Women's Health Across the Nations) Food Frequency Questionnaire (Appendix 1)

2. Do participants self-report eating less saturated fat (gms/day) after the intervention program than before?

Hypothesis: Participants will self-report consuming less saturated fat (gms/day) after the intervention program than before.

	Pre-test*	Post-test*
Saturated fat (gms/day)	√	√

\*Measured by change in grams/day of saturated fat using the SWAN Food Frequency Questionnaire

3. Do participants self-report participating in more minutes of physical activity per week after the intervention program than before?

Hypothesis: Participants will self-report participating in more minutes of physical activity per week after the intervention program than before.

	Pre-test*	Post-test**
Minutes/week of physical activity	√	√

Measured by a change in minutes/week of physical activity using the Hispanic Family Diabetes Project Enrollment Questionnaire for the participant with diabetes\* (Appendix 2) and the Hispanic Family Diabetes Project Follow up Questionnaire for the participant with diabetes \*\* (Appendix 3)

4. Does insulin resistance in participants improve after the intervention program compared to before the intervention program?

Hypothesis: Insulin resistance in participants will improve after the intervention program compared to before the intervention program.

- Measured by fasting plasma glucose (mg/dL) and insulin (mU/L) blood draws pre and post intervention.

- Calculation of insulin resistance using the homeostasis model assessment (HOMA-IR) which is derived from fasting plasma glucose (FPG) and insulin levels (Yokoyama et al, 2003).
- $\text{HOMA-IR} = \text{FIRI (fasting immunoreactive insulin) mU/L} \times \frac{\text{FPG mg/dL}}{405}$

	Pre-test*	Post-test*
Insulin resistance (HOMA-IR)	√	√

\*Measured by a change in insulin resistance using the HOMA-IR formula

5. Do participants improve their diabetes risk factors (fasting glucose, insulin, and HgbA1c) after the intervention program compared to before the intervention program?

Hypothesis: Participants will improve their diabetes risk factors (fasting glucose, insulin, and HgbA1c) after the intervention program compared to before the intervention program.

	Pre-test*	Post-test*
Fasting plasma glucose, insulin, and HgbA1c	√	√

\*Measured by a change in fasting plasma glucose (mg/dL), insulin (mU/L), and HgbA1c (%) blood draws

6. Do participants improve their risk factors for high density lipoprotein-cholesterol (HDL-cholesterol), low density lipoprotein-cholesterol (LDL-cholesterol), triglycerides (TG), and total cholesterol (TC) after the intervention program compared to before the intervention program?

Hypothesis: Participants will improve their risk factors for HDL-cholesterol,

LDL-cholesterol, TG, and TC after the intervention program compared to before the intervention program.

	Pre-test*	Post-test*
Fasting HDL-cholesterol, LDL-cholesterol, TG, and TC	√	√

\*Measured by fasting high density lipoprotein-cholesterol, low density lipoprotein-cholesterol, triglycerides, and total cholesterol blood draws (mg/dL)

#### Secondary Research Question

1. Do support participants self-report an increase in supportive behavior directed toward their partner with diabetes after the intervention program than before?

Hypothesis: Support participants will self-report an increase in supportive behavior directed toward their partner with diabetes after the intervention program.

	Pre-test*	Post-test**
Number of supportive activities	√	√

Measured by a change in number of supportive activities using the Hispanic Family Diabetes Project Enrollment Questionnaire for the support participant \* (Appendix 4) and the Hispanic Family Diabetes Project Follow up Questionnaire for the support participant \*\* (Appendix 5).

## CHAPTER 2 - REVIEW OF LITERATURE

Healthy People 2010, the comprehensive national health promotion and disease prevention agenda, established a number of goals intended to impact the health of our nation's citizens. Two in particular that relate to this study are: 1) eliminate health disparities, and 2) reduce diabetes and its economic burden (DHHS, 2000).

The attention to health disparities is in response to the overwhelming evidence that many minorities are being disproportionately impacted by major health problems. According to an Institute of Medicine (IOM) study, evidence of racial and ethnic disparities in health care remain even after adjustments are made for socioeconomic differences and health access-related factors (IOM, 2003). The study further indicates that health disparities are associated with poor outcomes for minority populations. The findings, from a study completed by Baumann and associates (2002), support the need for more effective interventions that promote healthy lifestyle if health disparities in low-income populations with chronic conditions are to be reduced. The purpose of their study was to examine health outcomes for persons with hypertension and diabetes who receive primary care at an urban community health center that serves primarily patients who are uninsured, ethnically diverse, and economically disadvantaged, and to compare these outcomes for disparities (Baumann et al, 2002). Compared with Blacks and Whites, a greater proportion of Hispanics were without insurance and had less than a high school education. The study showed that risk factors (smoking and obesity) for cardiovascular disease (CVD) exist at a higher rate among low-income adults with hypertension and diabetes compared with the general population. In addition, the study sample of individuals with diabetes had less optimal glycemic control compared to the general



population with only 36.6% of Blacks, 10% of Hispanics, and 10.5% of Whites achieving optimal glycemic control (glycosylated hemoglobin (HgbA1c) < 7%) (Baumann et al, 2002). The striking differences underscore the urgent and critical need for prevention programs to address lifestyle behavior for this population (Baumann et al, 2002).

Current research by Jiang and associates (2005), who studied the relationship between race/ethnicity and hospital readmissions for diabetes related conditions in 5 states also supports the work by Baumann et al (2002). After adjusting for patient clinical, demographic, and socioeconomic characteristics and hospital attributes, the risk-adjusted likelihood of a 180-day hospital readmission was significantly lower for adult non-Hispanic Whites than for Hispanics across all 3 payers (Medicaid, Medicare, private insurance) (Jiang et al, 2005). Within each payer, Hispanics from low-income communities had the highest risk of hospital readmission. Among Medicare beneficiaries, Blacks and Hispanics had higher percentages of readmission for microvascular disease and acute complications, while Whites had higher percentages of readmission for macrovascular conditions. Readmission diagnoses varied by race/ethnicity, with Hispanics and Blacks at higher risk for those complications more likely preventable with effective post-discharge care (Jiang et al, 2005). The findings suggest that interventions should be designed for racial/ethnic minorities, particularly among the elderly, to improve the quality of outpatient care and reduce potentially preventable readmissions for diabetes complications (Jiang et al, 2005).

An extensive review of literature, specifically searching for interventions designed for managing diabetes in racial/ethnic minorities, found little research

combining nutrition, physical activity, self-care management, and the inclusion of a support individual into one educational intervention program in Spanish for Hispanics with diabetes. Clearly, all 4 entities are interrelated and crucial if an individual is to be successful in managing their disease. Currently there are only 4 research studies, that will be discussed later in detail, that address each of these 4 areas or in some combination of 1-3 areas (Elshaw et al, 1994; Brown and Hanis, 1999; Banister et al, 2004; Lemon et al, 2004) (Table 2.3). However, only 1 study by Brown and colleagues (1999) utilized all 4 components. Unfortunately, they did not address the impact of social support on outcome variables and 50% of the participants had dropped out by the end of the year long intervention, which included 26 sessions.

The following review of the literature will be divided into 4 sections and will serve to provide a background as to what has been done, and is currently being done, to decrease the incidence and to help in the managing of diabetes in the general population and then more specifically in the Hispanic population. The first section covers research and recommended guidelines in the area of chronic disease prevention with particular emphasis placed on the role of nutrition, physical activity, and lifestyle modification. The second section will cover research and programs in the area of diabetes treatment, again focusing on nutrition and physical activity; however, studies in diabetes self-care management and the use of social support have also been included here. Special emphasis will be given to the 4 diabetes educational intervention studies mentioned above and outlined in Table 2.3. These studies focus on individuals who are already being treated for diabetes and 3 of the 4 studies focused on the Hispanic population with diabetes. Third, 3 health promotion programs will be highlighted that focus primarily on

the Hispanic population. Each program offers a unique approach for helping to educate this population about diabetes. Finally, this review will examine what is being done in the state of Oregon to help reduce the burden of diabetes in the general population of which Hispanics/Latinos are the largest growing ethnic group.

## **CHRONIC DISEASE PREVENTION**

Compelling evidence from epidemiologic studies indicates that major chronic diseases, including coronary heart disease (CHD), type 2 diabetes, stroke, and some forms of cancer are heavily influenced by dietary and lifestyle factors (Willett, 2002). Modifiable behavioral factors, including specific aspects of diet, overweight, inactivity, and smoking, account for 70% of stroke and colon cancer, 80% of CHD, and over 90% of type 2 diabetes (Willett, 2002). To help emphasize the importance of reducing modifiable risk factors 2 large studies will be reviewed, the Diabetes Prevention Program (DPP Research Group, 2002) and the Adult Treatment Panel III (ATP III, 2001). Following this, studies that focus on the role of nutrition and physical activity in preventing chronic disease will be examined.

### **Diabetes Prevention Program (DPP)**

The importance of reducing modifiable risk for diabetes was confirmed by the results of a landmark National Institutes of Health (NIH), Diabetes Prevention Program (DPP) randomized clinical trial (DPP Research Group, 2002). This clinical trial of 3,234 people (1,043 male, 2,191 female) compared diet and exercise to treatment with metformin in people with glucose intolerance to determine the impact on decreasing type

2 diabetes. All participants were overweight (body mass index (BMI) =  $34.0 \pm 6.7$  kg/m<sup>2</sup>), had impaired glucose tolerance, and 16% of the participants were Hispanic. Participants were randomly assigned to an intensive lifestyle intervention aimed at reducing their risk of getting type 2 diabetes. The primary outcome of the study was diabetes, diagnosed using an annual oral glucose-tolerance test or a semiannual fasting plasma glucose test. The intensive lifestyle arm of the intervention consisted of physical activity (walking or other moderate exercise) for 30 minutes per day and training in diet and behavior modification in order to reduce body weight by 5-7%. Participants in this group reduced their risk of developing type 2 diabetes by 58%; while participants in the metformin group reduced their risk of developing type 2 diabetes by 31%. This is the first clinical trial of Americans at high risk of diabetes to show that regardless of ethnicity, race, or gender, lifestyle changes in diet and exercise and a small reduction in weight can dramatically prevent or delay type 2 diabetes. In addition, lifestyle change worked better than using medication.

### Adult Treatment Panel III

Based on evidence that adequate control of blood glucose and lipids can decrease the risk of adverse health outcomes, national guidelines that define optimal clinical outcomes based on patient risk factors have been developed (ATP III, 2001). The third National Cholesterol Education Program Adult Treatment Panel (ATP III) report updates the existing recommendations for clinical management of high blood cholesterol. Some of the guidelines in this report are outlined in Tables 2.1 & 2.2.

Dyslipidemia is often found in persons with type 2 diabetes; therefore, monitoring

of blood lipids is crucial. Despite the preponderance of evidence that adequate control of blood glucose and lipids delays or prevents diabetic complications, less than 10% of adults with diabetes meet the recommendations for blood glucose, total blood cholesterol, and blood pressure (Saydah et al, 2004).

**Table 2.1 Adult Treatment Panel III classification of LDL, total, and HDL-cholesterol (mg/dL)\***

<u>LDL cholesterol</u> < 100 100-129 130-159 160-189 ≥ 190	Optimal Near or above optimal Borderline high High Very high
<u>Total cholesterol</u> < 200 200-239 ≥ 240	Desirable Borderline high High
<u>HDL cholesterol</u> < 40 ≥ 60	Low High

\*LDL=low density lipoprotein, HDL=high density lipoprotein

**Table 2.2 Clinical identification of the Metabolic Syndrome**

Risk Factor	Defining Level
<u>Abdominal obesity</u> Men Women	<u>Waist circumference</u> > 40 in > 35 in
Triglycerides	≥ 150 mg/dL
<u>HDL cholesterol</u> Men Women	< 40 mg/dL < 50 mg/dL
Blood pressure	≥ 130/85 mm Hg
Fasting glucose	≥ 110 mg/dL

Adapted from: <http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf>

## Role of Nutrition

A multitude of research has been done to evaluate the role of nutrition in the prevention of type 2 diabetes. The health benefits of following a proper diet not only include the decreased risk of type 2 diabetes but a decreased risk of other major chronic diseases as well.

Government Recommendations. The 2005 Dietary Guidelines for Americans (DHHS-USDA) provides evidence-based advice to promote health and to reduce risk for major chronic diseases, such as diabetes, through diet and physical activity. Major causes

of morbidity and mortality in the United States (U.S.) are related to a sedentary lifestyle and poor diet. Some of the key recommendations of these guidelines include:

- Consume a variety of nutrient-dense foods and beverages within and among the basic food groups while choosing foods that limit the intake of saturated and trans fats, cholesterol, added sugars, salt, and alcohol.
- To maintain body weight in a healthy range, balance calories from foods and beverages with calories expended.
- Choose a variety of fiber rich fruits, vegetables, and whole grains often while staying within energy needs (a minimum of 5 servings per day of fruits and vegetables, and 3 or more ounce-equivalents of whole grain products per day). One of the health benefits of soluble fiber is that it helps prevent blood glucose from rising too rapidly.
- Consume less than 10% of energy from saturated fat and less than 300 mg/day of cholesterol, and keep trans fatty acid consumption as low as possible.
- Keep total fat intake between 20-35% of energy, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils.
- When selecting and preparing meat, poultry, dry beans, and milk or milk products, make choices that are lean, low-fat, or fat-free.
- Limit intake of fats and oils high in saturated and/or trans fatty acids, and choose products low in such fats and oils.
- Choose and prepare foods and beverages with little added sugars or caloric sweeteners.

Observational Research. The benefits of whole grain foods cannot be over estimated. Prospective cohort studies have consistently found whole grain intake to be inversely associated with the risk of type 2 diabetes and CVD (Liu, 2003; Hu, 2003). This point was illustrated by Heaton and colleagues (1988) who compared intake of coarsely milled vs. finely milled wheat flour to insulin responses (peak concentration and area under curve). When healthy volunteers ate isocaloric wheat-based meals, their

plasma insulin responses increased in a stepwise sequence: whole grains < cracked grains < coarse flour < fine flour. Intact grains slowed the digestion of carbohydrate, as measured in vitro by pancreatic amylase, resulting in lower glycemic and insulinemic responses to carbohydrate. The 3-dimensional structure of intact whole grains was more important than the fiber content in determining the glycemic response to carbohydrate. The authors concluded that the increased insulin response to finely ground flour may be relevant to the etiology of diseases associated with hyperinsulinemia. In addition, milling removes most of the bran and much of the germ of the whole grain and results in a refined grain product that has lost a substantial amount of dietary fiber, vitamins, minerals, essential fatty acids, and phytochemicals, and contain more starch (Hu, 2005). Due to the loss of the outer bran layer and pulverization of the endosperm, refined grains are digested and absorbed more rapidly than are whole grain products and; thus, tend to cause more rapid and larger increases in levels of blood glucose and insulin than do whole grain products (Hu, 2005).

Nuts and peanut butter have also been independently associated with a significant decrease in risk of type 2 diabetes in women. In a prospective study by Jiang et al (2002), the association between nut consumption and risk of type 2 diabetes in a large cohort of women from the Nurses' Health Study was examined. The Nurses' Health Study was established in 1976 when 121,700 female registered nurses, aged 30 to 55 years and from 11 states, completed a mailed questionnaire designed to study etiologies of cancer, heart disease, and other major illnesses (Jiang et al, 2002). Information on lifestyle, health behaviors, and disease status has been collected on biennially mailed questionnaires since 1976 (Jiang et al, 2002). For the purposes of this analysis women

with a history of diabetes, CVD, and cancer were excluded, which left 83,818 participants remaining in the analysis. These women completed a validated dietary questionnaire at baseline in 1980, and were followed up for 16 years, with the main outcome measure being incident cases of type 2 diabetes (Jiang et al, 2002). In this large prospective cohort study of women, the consumption of nuts and peanut butter was inversely associated with risk of type 2 diabetes ( $p$  for trend  $< 0.001$ ). Nuts may protect against type 2 diabetes through a number of mechanisms; they are a source of fiber and magnesium, which decreases insulin demand and resistance, and they are high in polyunsaturated and monounsaturated fats, which may improve glucose and insulin homeostasis (Jiang et al, 2002).

The glycemic load of a diet (the product of the glycemic index value of a food and its carbohydrate content) and specific dietary patterns may also lead to increased risk of chronic disease. In prospective cohort studies, high glycemic load diets (which represent both the quality and quantity of carbohydrates consumed) have been associated with significantly higher risk of developing CVD and type 2 diabetes (Liu et al, 2000; Salmeron et al, 1997). Although numerous studies have examined the relationship between intake of individual foods or nutrients and risk of chronic disease, less research has been done on the effects of dietary patterns (Hu, 2005). Two major dietary patterns, the Western and the Prudent diets, have been identified through factor analysis of food consumption (Hu, 2005). The Western pattern (higher intakes of red and processed meats, sweets and desserts, french fries, and refined grains) has been consistently associated with increased risk of diabetes, CHD, stroke, and colon cancer, whereas the



Prudent pattern (higher intakes of fruits, vegetables, legumes, fish, poultry, and whole grains) has been associated with a lower risk (Hu, 2005).

### Role of Physical Activity

Along with nutrition, research efforts have been directed toward defining the role of physical activity in the prevention of type 2 diabetes. The health benefits of regular physical activity include the reduction of chronic disease risk factors and conditions that relate to diet as well. Among these are type 2 diabetes, high blood pressure, stroke, coronary artery disease, colon cancer, and osteoporosis (Pate et al, 1995; Shephard, 2001).

Government Recommendations. The U.S. Surgeon General's report recommended that most individuals accumulate  $\geq 30$  minutes of moderate intensity activity on most, ideally all, days of the week to effect favorable health-related benefits, such as weight loss, blood pressure reduction, and favorable lipid and lipoprotein changes (DHHS, 1996). The key recommendation for physical activity from the 2005 Dietary Guidelines for Americans is to engage in regular physical activity and reduce sedentary activities to promote health, psychological well-being, and a healthy body weight. These recommendations are similar to those of the American Diabetes Association (~30 minutes aerobic activity 3 times/week) and the American College of Sports Medicine (30-60 minutes/day most days of the week). The 2005 Dietary Guidelines for Americans recommendations are listed below:

- To reduce the risk of chronic disease in adulthood engage in at least 30 minutes of moderate intensity physical activity, above usual activity, at work or home on most days of the week.

- For most people, greater health benefits can be obtained by engaging in physical activity of more vigorous intensity or longer duration.
- To help manage body weight and prevent gradual, unhealthy body weight gain in adulthood, engage in ~60 minutes of moderate-to-vigorous intensity activity on most days of the week while not exceeding energy intake to maintain current weight.
- To sustain weight loss in adulthood, participate in at least 60-90 minutes of daily moderate intensity physical activity while not increasing energy intake.

Despite the overwhelming evidence that physical activity is associated with a range of health benefits, and its absence can have harmful effects on health and well-being, more than half of U.S. adults do not participate in physical activity at a level recommended as beneficial to health (MMWR Weekly, 2005).

Observational Research. To help support the 2005 Dietary Guidelines for Americans recommendation that physical activity decreases the risk of chronic disease, Paffenbarger and associates (1993) analyzed changes in lifestyles of Harvard college alumni and the associations of these changes with mortality. Men who were 45 to 84 years of age in 1977 and who had reported no life threatening diseases on questionnaires completed in 1962 or 1966 and again in 1977 were classified according to lifestyle change characteristics between the 1<sup>st</sup> and 2<sup>nd</sup> questionnaires (Paffenbarger et al, 1993). Changes in their level of physical activity, cigarette smoking, blood pressure, and body weight were analyzed and the relation of these factors to mortality between 1977 and 1985. Of the 10,269 men, 476 died during this period. Beginning moderately vigorous sports activity (at an intensity of  $\geq 4.5$  metabolic equivalents) was associated with a 23% lower risk of death than not taking up moderately vigorous sports (Paffenbarger et al, 1993). A metabolic equivalent (MET) is a unit of intensity equal to energy expenditure at

rest; for example, physical activity at 3 METs uses three times as much energy as stationary sitting (Sigal et al, 2004).

Research by Fulton-Kehoe and associates (2001), who studied the relationship between physical activity and risk of chronic disease as part of the San Luis Valley Diabetes Study, also supports the 2005 Dietary Guidelines for Americans. In this study, the association between physical activity and type 2 diabetes in Hispanic and non-Hispanic White subjects with diabetes was compared to control subjects with normal glucose tolerance. This study included approximately equal numbers of Hispanic and non-Hispanic White subjects and both males and females. The results showed that after adjustment for ethnicity, gender, and family history, persons with higher levels of physical activity were 25-50% less likely to have type 2 diabetes. After controlling for body mass index ( $\text{kg/m}^2$ ), the association of physical activity and type 2 diabetes became nonsignificant in most models; therefore, the relationship between physical activity and the risk of diabetes did not vary by the degree of obesity in this population. The investigators examined the interactions of ethnicity (Hispanic vs. non-Hispanic Whites) with all physical activity measures (i.e., work activity, leisure activity, etc.), and found that the association was stronger among Hispanic than non-Hispanic White subjects, but none of the ethnic differences were statistically significant. In summary, the authors found that high levels of physical activity were associated with lower odds of type 2 diabetes and this relationship may be stronger in Hispanic subjects.

Physical activity and risk of diabetes was also investigated by Hu and colleagues (2003) in a prospective cohort study examining the relationship between various sedentary behaviors, especially prolonged television watching, and risk of obesity and

type 2 diabetes in women. The main outcome measures were onset of obesity and type 2 diabetes mellitus. The diabetes analysis included 68,497 women from 11 states in the Nurses' Health Study who at baseline were free from diagnosed diabetes mellitus, CVD, or cancer. During 6 years of follow up, time spent watching television was positively associated with risk of obesity and type 2 diabetes. For every 2 hour/day increment in television watching there was a 14% increase in risk of diabetes; however, for every 1 hour/day of brisk walking there was an overall 34% reduction in diabetes. The researchers estimated that in this cohort, 43% of new cases of diabetes could be prevented by adopting a relatively active lifestyle ( $< 10$  hrs/week of television watching and  $\geq 30$  mins/day of brisk walking) (Hu et al, 2003).

Similar conclusions were reported by Kelm and associates (2004) in their review of America's obesity epidemic. An increased incidence of type 2 diabetes was associated with inactivity in large population studies, and participation in lifestyle modification programs to increase physical activity led to a reduced incidence of the disease. The positive effects of physical activity on decreasing risk of type 2 diabetes may be partly due to increased skeletal muscle contractions that mimic the action of insulin, thereby increasing glucose uptake and metabolism (Kelm et al, 2004). Additional positive effects of physical activity on glucose control include enhanced insulin sensitivity and improvement in glucose tolerance in healthy individuals (Araujo-Vilar et al, 1997). Exercise training decreases hepatic and muscle insulin resistance and increases glucose disposal through a number of mechanisms that were extensively reviewed by Ivy and associates (1999), and include the following:

- Increased post-receptor insulin signaling.
- Increased glucose transporter protein and messenger RNA.
- Increased activity of glycogen synthase and hexokinase.
- Decreased release and increased clearance of free fatty acids.
- Increased muscle glucose delivery due to increased muscle capillary density.
- Changes in muscle composition favoring increased glucose disposal.

Experimental Research. A longitudinal study completed by Bergman and associates (1999) sought to evaluate the hypotheses that alterations in glucose disposal rate due to endurance training are the result of changed net glucose uptake by active muscle and that blood glucose is shunted to working muscle during exercise requiring high relative power output (Bergman et al, 1999). In this study, 9 healthy sedentary male subjects aged 19-33 years were recruited and tested for leg net glucose uptake before and after 9 weeks of cycle ergometer training, at 5 times per week and at 75%  $\text{VO}_2$  peak. Data on the effects of exercise and training on limb and whole body substrate utilization were obtained by pulmonary indirect calorimetry, measurements of arteriovenous differences of glucose,  $\text{CO}_2$  and  $\text{O}_2$ , isotope tracers, and muscle biopsies. The results showed that high power output exercise (65%  $\text{VO}_2$  peak) depends on carbohydrate derived fuel sources and that blood glucose is shunted from inactive tissues to active muscle during hard exercise regardless of training state. Although blood glucose may be directed to working muscle during exercise, the gain in net glucose uptake by working muscle during hard exercise is small compared with the gain in total body carbohydrate oxidation. Thus, the apparent sparing of glucose uptake in response to gradations in power output are viewed as a means to maintaining glycemia during hard exercise, which

requires high rates of carbohydrate oxidation (Bergman et al, 1999).

Despite the knowledge that physical activity is associated with a range of health benefits, and its absence can have harmful effects on health and well-being, the research suggests that physical activity levels are low for most Americans (MMWR Weekly, 2005). For example, in 2002, 38% of adult Americans engaged in no leisure-time physical activity (NHIS, 2002). Hispanics are reported to be less active than Whites, females are generally less active than men, and individuals with lower incomes and less education tend to be less physically active as compared to those with more education and with higher incomes (DHHS, 2000). In a secondary analysis of data from the Third National Health and Nutrition Examination Survey (NHANES III) (1988-1994), after adjusting for age, 39% of Mexican-Americans engaged in no leisure-time physical activity (Wood, 2002).

### Lifestyle Modification

It has been estimated that more than 90% of cases of type 2 diabetes could be prevented by adopting a healthful diet and lifestyle that includes weight loss, regular exercise, modification of diet, abstinence from smoking, and the consumption of limited amounts of alcohol (Hu et al, 2001). In order to adopt a healthy diet and lifestyle, individuals at high risk for diabetes need to be educated on the ramifications of the disease and the benefits of lifestyle changes that have been shown to be successful in decreasing the risk of type 2 diabetes.

Individuals with impaired glucose tolerance (IGT) have a high risk of developing type 2 diabetes. To examine the effect of diet and exercise on IGT and delay of type 2

diabetes Pan and colleagues (1997) randomly assigned 577 participants with IGT to either a control group or to one of three treatment groups: diet only, exercise only, or diet plus exercise. Follow up evaluation examinations were conducted at 2 year intervals over a 6 year period to identify which participants developed type 2 diabetes. The cumulative incidence of diabetes at 6 years was 67.7% in the control group compared with 43.8% in the diet group, 41.1% in the exercise group, and 46% in the diet plus exercise group (Pan et al, 1997). When analyzed by clinic, each of the treatment groups differed significantly ( $p < 0.05$ ) from the control clinics (Pan et al, 1997).

A meta-analysis of randomized controlled trials performed by Yamaoka and Tango (2005), also supports the efficacy of lifestyle education for preventing type 2 diabetes in individuals at high risk for the disease. In this analysis, 8 studies were identified that met the strict inclusion criterion for 2 hour plasma glucose and 5 studies were identified that met the criterion for the incidence of diabetes. All were randomized controlled trials that were  $\geq 6$  months in length with lifestyle education that included a dietary intervention. The difference in mean reduction of 2 hour plasma glucose from baseline to the 1 year follow up and relative risk of the incidence of diabetes in the lifestyle education group versus the control group were assessed. The lifestyle education intervention reduced 2 hour plasma glucose by 0.84 mmol/L (15.12 mg/dL) compared with the control group and the 1 year incidence of diabetes was reduced by ~50% compared with the control group (Yamaoka and Tango, 2005).

In summary, research shows that by modifying lifestyle behaviors such as diet and physical activity level, that the risk of type 2 diabetes can be decreased regardless of

ethnicity, race, or gender. These same lifestyle behaviors are also essential in the treatment of the disease, again regardless of ethnicity, race, or gender. Although a number of studies have been done in the area of chronic disease prevention, studies designed specifically for the Hispanic population are limited.

## **DIABETES TREATMENT**

The goal of treatment in type 2 diabetes is to achieve and maintain near normal blood glucose levels, optimal lipids, and normal blood pressure levels in order to prevent or delay microvascular, macrovascular, and neural complications. To help emphasize the importance of treating the individual with diabetes in order to prevent macrovascular and microvascular complications, the United Kingdom Prospective Diabetes Study (UKPDS) will be reviewed along with studies that focus on the role of nutrition, physical activity, self-care management, and social support in treating diabetes.

The benefits of treating diabetes cannot be over estimated. When diabetes is diagnosed at an early stage, morbidity and mortality can be limited through a number of evidence-based, cost-effective treatment strategies some of which include (DHS, 2005):

- Glucose control - with diet, exercise, and medication (if necessary). For every 1 point decrease in HgbA1c value there is a 40% reduction in the risk of microvascular (eye, kidney, and nerve disease) complications of diabetes.
- Blood pressure control – for every 10 millimeters of mercury (mm Hg) reduction in systolic blood pressure, the risk for any complication related to diabetes is reduced by 12%.
- Blood lipid control – dyslipidemia is often found in persons with type 2 diabetes; thus, adequate control of blood lipids can reduce CVD complications by 20-50%.
- Preventative care for eyes, kidneys, feet – detecting and treating diabetic eye disease can reduce the development of severe vision loss by ~50-60%; detecting and treating early diabetic kidney disease by lowering blood pressure can reduce



the decline in kidney function by 30-70%; a comprehensive foot care program can reduce amputation rates by 45-85%.

#### United Kingdom Prospective Diabetes Study (UKPDS)

In 1998, the UKPDS demonstrated conclusively that elevated blood glucose levels cause long-term complications in type 2 diabetes (Mahan and Escott-Stump, 2000). In this study 5,102 newly diagnosed individuals with type 2 diabetes were followed for 10-11 years. Participants were randomized into one of 2 groups: Conventional treatment - with diet therapy, achieved an average HgbA1c of 7.9%; and Intensive treatment - initially treated with sulfonylureas to decrease blood glucose, achieved an average HgbA1c of 7.0%. In the intensive intervention group, the risk of macrovascular disease decreased by 16% and the microvascular complications rate decreased significantly by 25% (Mahan and Escott-Stump, 2000). For every 1 point decrease in the HgbA1c level there was a 37% reduction in the risk of microvascular complications of diabetes (Stratton et al, 2000). The optimal clinical outcome for HgbA1c for individuals with diabetes is < 7%; a change in treatment is indicated for a value > 8% (Mahan and Escott-Stump, 2000).

#### Role of Nutrition Therapy

Today there is evidence-based outcomes research to document the clinical effectiveness of medical nutrition therapy (MNT) in diabetes management. Franz and colleagues (1995) completed a prospective, randomized, controlled clinical trial of 2 levels of MNT on metabolic control in persons newly diagnosed with or currently under treatment for type 2 diabetes. Of the 179 adult men and women, 85 were assigned

randomly to basic nutrition care, a single visit with a dietitian; and 94 were assigned to practice guidelines nutrition care (PGC), an initial visit with a dietitian followed by 2 visits during the first 6 weeks of the study. Additionally, 62 adults with type 2 diabetes who had no contact with a dietitian were identified as a non-random comparison group. All subjects were evaluated at the time of enrollment and at 3 and 6 months post enrollment. HgbA1c levels at 6 months were significantly less ( $p < 0.001$ ) than at baseline for both the basic care nutrition and PGC groups, while HgbA1c levels were unchanged in the control group receiving no nutrition intervention (Franz et al, 1995).

The impact of nutrition education in improving glycemic control has also been examined in 2 research studies that focused primarily on nutrition education as an intervention (Elshaw et al, 1994; Lemon et al, 2004), see Table 2.3. In the 1<sup>st</sup> study, Elshaw and colleagues (1994) recruited 152 Mexican-American men and women over 50 years of age with type 2 diabetes and randomly assigned them to a diabetes education program group or to a control group. The nutritional intake of participants in both groups was assessed using 24-hour dietary recalls. For the experimental group, diet was assessed prior to, during, and after the diabetes education program to measure the impact of an intensive, culturally-specific diabetes education program on eating habits and to assess nutrient consumption relative to the 1989 Recommended Dietary Allowances (RDA). The researchers hypothesized that participation in the education program would bring the dietary choices of the experimental group closer to the guidelines recommended by the American Diabetes Association (ADA), while dietary choices of the control group would remain constant over time (Elshaw et al, 1994). Participants in the diabetes educational group attended weekly educational sessions (2 hours/session) in groups of 8

**Table 2.3 Summary of diabetes intervention published research**

Study	Participants	Intervention	Length	Outcome Variables	Sig Diff ( $p < 0.05$ )
Elshaw et al. 1994	n=78, T 74% completion  n=74, C 62% completion  (elderly Mexican- Americans w/type 2 diabetes)	T=Nutrition  C=no intervention	T=weekly education sessions for 8 weeks  (2h/session)	Body weight loss	T & C (males)  C=females
				Decreased energy intake	C=males
				Decreased cholesterol intake	C=females
Brown and Hanis 1999	n=125, T 50% completion  n=122, C  (n=Mexican- Americans w/type 2 diabetes & support person)	T=Nutrition, exercise, & self-mgmt C=no intervention	T=12 mo  (26 sessions over 1 y, 2h/ session)	HgbA1c (%)	no
				Fasting blood glucose (mg/dL)	yes at 6 mo (signif. level not specified)
Banister et al. 2004	n=70, T  No C  (Mainly Hispanics or African Americans w/type 2 diabetes)	T=Diabetes self- mgmt  No C	12 mo  -a 4 h group class offered monthly -followed by $\geq 1$ individual consultation w/RD -no support meetings  (mean hours of attending all 3= 6.5 +/- 3.0)	HgbA1c (%)	yes
				Decrease medication use	yes
				Body mass index (BMI)	no
Lemon et al. 2004	n=244, T (184 finished)  No C  (non-Hispanic adults w/type 2 diabetes)	T=Nutrition + counseled by 59 RDs in outpatient and inpatient clinic settings  No C	6 mo  RDs spent an avg of 111 +/- 55 mins w/each subject & met w/subjects an avg of 2.1 +/- 1.0 times	HgbA1c (%) Fasting plasma glucose (mmol/L) 5-year CHD risk (%) Diet/lifestyle questionnaire Exercise assessment	yes yes  yes yes  yes

T=Treatment; C=Control; RD=Registered Dietitian; HgbA1c=Glycosylated hemoglobin

to 10 participants for a total of 8 weeks, while the control group received no diabetes education. The outcome variables in this study were body weight loss, decreased energy and cholesterol intake. Although several positive changes occurred in the experimental group (a trend toward decreased energy intake for both males and females, a trend toward decreased cholesterol intake for females and a significant weight loss for males) simply educating patients about diabetes complications and the diabetic diet was not enough to produce significant changes in eating behavior in the short-term.

The other major research study to focus primarily on nutrition education as an intervention was done by Lemon et al (2004), see Table 2.3 In this prospective, non-controlled descriptive study, 184 physician-referred non-Hispanic adults with type 2 diabetes received nutrition counseling from RDs in outpatient and inpatient settings (Lemon et al, 2004). The intervention lasted 6 months and RDs spent an average of  $111 \pm 55$  minutes with each participant and met with participants an average of  $2.1 \pm 1.0$  times. The main outcome measures of glycemic control, coronary heart disease risk factors, and self-management behaviors (diet, exercise, blood glucose self-monitoring frequency), were measured at baseline, 3 months, and 6 months. After 6 months, patients with diabetes receiving nutrition counseling had significant reductions ( $p < 0.0001$ ) in HgbA1c (%) (baseline  $8.7 \pm 2\%$ , after 6 months  $7.0 \pm 2\%$ ), fasting plasma glucose (mmol/L) (baseline  $11.4 \pm 4.9$  mmol/L or  $205.2 \pm 88.2$  mg/dL; after 6 months  $8.3 \pm 4.4$  mmol/L or  $149.4 \pm 79.2$  mg/dL), 5 year CHD risk (%), diet, and exercise compared to baseline (Lemon et al, 2004).

These clinical interventions are supported by meta-analysis studies that have looked at diabetes education and have shown that nutrition interventions have the largest

statistically significant effect on metabolic control (Padgett et al, 1988; Brown, 1990).

Clearly, nutrition education is necessary in the treatment of diabetes.

Dietary Recommendations. One of the main goals of nutrition education for individuals with diabetes is to achieve and maintain optimal glycemic control to reduce the morbidity and mortality associated with the disease. Many misconceptions exist today concerning nutrition recommendations for individuals with diabetes. Moreover, in clinical practice, nutrition recommendations that have little or no supporting evidence are still being given to person with diabetes (ADA, 2004). The American Diabetes Association (ADA) issued a position statement in 2004 that provides evidence-based principles and recommendations for diabetes medical nutrition therapy. Some of their key recommendations include:

- Foods containing carbohydrate from whole grains, fruits, vegetables, and low-fat milk should be included in a healthy diet.
- With regard to the glycemic effects of carbohydrates, the total amount of carbohydrate in meals or snacks is more important than the source or type.
- As sucrose does not increase glycemia to a greater extent than isocaloric amounts of starch, sucrose and sucrose-containing foods do not need to be restricted by people with diabetes; however, they should be substituted for other carbohydrate sources.
- Less than 10% of energy intake should be derived from saturated fats. Some individuals (i.e., persons with LDL-cholesterol  $\geq 100$  mg/dL) may benefit from lowering saturated fat intake to  $< 7\%$  of energy intake.
- Dietary cholesterol intake should be  $< 300$  mg/day. Some individuals (i.e., persons with LDL-cholesterol  $\geq 100$  mg/dL) may benefit from lowering dietary cholesterol to  $< 200$  mg/day.
- In insulin resistant individuals, reduced energy intake and modest weight loss improve insulin resistance and glycemia in the short-term.

Many people with diabetes also have hypertension and dyslipidemia making reductions in dietary intake of saturated fat, cholesterol, and sodium desirable (ADA, 2004). Therefore, the emphasis of nutrition therapy for type 2 diabetes is on lifestyle strategies to reduce blood pressure, dyslipidemia, and glycemia (ADA, 2004). Additionally, nutrition recommendations for people with diabetes should be individualized, with consideration given to the individual's usual food and eating habits, ethnicity, metabolic profile, treatment goals, and desired outcomes.

Due to the concern about CHD for persons with diabetes the recent recommendations from the National Cholesterol Education Program expert panel should also be followed (ATP III, 2001). One of the new features of the ATP III is that it raises persons with diabetes and without CHD, to the level of CHD risk equivalent; in other words, they carry a risk for major coronary events equal to that of established CHD. Therefore, the blood LDL-cholesterol goal for individuals with diabetes is  $< 100$  mg/dL. If the LDL-cholesterol level is  $\geq 100$  mg/dL then the Therapeutic Lifestyle Changes (TLC) diet should be implemented. The composition of the TLC diet is outlined in Table 2.4. Additional therapeutic options for enhancing LDL-cholesterol lowering include increasing intake of viscous (soluble) fiber to 10-25 gms/day and the intake of 2 gms/day plant stanol/sterols.

Despite the overwhelming evidence stressing the importance of a healthy diet in the treatment of diabetes, recent surveys in the U.S. have shown that many persons with type 2 diabetes do not follow dietary recommendations set by the American Diabetes Association for the treatment of the disease. Only 64% of individuals with diabetes “always” or “usually” followed diet plans, according to a representative national sample

**Table 2.4 Composition of the Therapeutic Lifestyle Changes (TLC) Diet**

Essential Components	Recommendation
Saturated fat*	< 7% of total calories
Polyunsaturated fat	up to 10% of total calories
Monounsaturated fat	up to 20% of total calories
Total fat	25-35% of total calories
Cholesterol	< 200 mg/day
Carbohydrate <sup>†</sup>	50-60% of total calories
Protein	~15% of total calories
Dietary fiber	20-30 grams per day
Total calories (energy) <sup>‡</sup>	Balance energy intake and expenditure to maintain desirable body weight/prevent weight gain

\**Trans* fatty acids are another LDL-raising fat that should be kept at a low intake.

<sup>†</sup>Derived predominantly from whole grains, fruits, and vegetables.

<sup>‡</sup>Daily energy expenditure should include enough moderate exercise to expend at least 200 kcal/day.

Adapted from: <http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf>

of 2,056 individuals with diabetes (Ruggiero et al, 1997). In addition, research has shown that in people with diabetes the most difficult component of their self-care regimen is adherence to a healthful diet (Sullivan and Joseph, 1998). Additionally, people with diabetes report to be resistant to dietary change when compared to people with other chronic diseases (Savoca and Miller, 2001).

NHANES III used food frequency analysis and 24-hour recalls to evaluate macronutrient consumption in 1,480 persons with type 2 diabetes (Nelson et al, 2002). Sixty-two percent of respondents ate fewer than 5 servings of fruits and vegetables per day, and almost two-thirds consumed > 30% of their daily energy from fat and > 10% of total energy from saturated fat (Nelson et al, 2002). Mexican-Americans ate a higher number of fruits and vegetables and a lower percentage of total energy from fat and saturated fat (Nelson et al, 2002). In a separate study looking at the eating behaviors of individuals without diabetes and low educational attainment, Winkleby and associates (1994) found increasing fat consumption in Hispanics at higher levels of acculturation.

Other studies support the findings from NHANES III, indicating that the diets of most individuals with diabetes are less than optimal. Neuhouser and colleagues (2002) examined 1,782 patients with diabetes, dyslipidemia, CVD, or hypertension attending an outpatient clinic. They found that patients with diabetes consumed significantly ( $p < 0.01$ ) more of their energy from fat than the other groups (Neuhouser et al, 2002).

Participants in this sample with diet-modifiable disorders reported that they are motivated to eat less fat, but most consume a diet high in fat and low in fruits and vegetables and engage in very little exercise. These results support those reported by Schmidt and colleagues (1994), who also evaluated nutrition intake in subjects with type 2 diabetes. Participants in their study consumed between 34-35% of their total energy intake as fat. Clearly, reducing dietary fat intake is a challenge for many individuals with diabetes.

#### Role of Physical Activity

For decades, exercise has been considered a cornerstone of diabetes management, along with diet and medication (Sigal et al, 2004). However, high quality evidence on the importance of exercise in the treatment of diabetes was lacking until recent years (Sigal et al, 2004). Research efforts have not only been directed toward defining the role of physical activity in the prevention of type 2 diabetes but they have also been directed toward the role of physical activity in the treatment of the disease. In a review completed by Sigal and associates (2004), they summarized that regular physical activity is imperative to sustaining glucose lowering effects and improving insulin sensitivity in individuals with type 2 diabetes. Although individuals with type 2 diabetes are usually insulin resistant, they are not resistant to the stimulatory effects of exercise on glucose



utilization (Sigal et al, 2004). The functional recruitment of GLUT4 (a glucose transporter) coupled with elevated circulating glucose levels can actually lead to a greater rate of glucose utilization by muscle of individuals with type 2 diabetes (Sigal et al, 2004). Individuals with type 2 diabetes retain the capacity to translocate GLUT4 to the muscle cell membrane in response to exercise (Kennedy et al, 1999).

Experimental Research. Improved insulin sensitivity has also been reported in individuals with diabetes who become more physically active. In a cross-sectional study, Mayer-Davis and colleagues (1998) recruited 1,467 men and women of African American, Hispanic, and non-Hispanic White ethnicity aged 40-69 years, with glucose tolerance ranging from normal to mild type 2 diabetes. The objective of this study was to determine whether habitual, non-vigorous physical activity, as well as vigorous and overall activity, is associated with better insulin sensitivity as measured by an intravenous glucose tolerance test. The mean insulin sensitivity for individuals who participated in vigorous activity (metabolic equivalent  $\geq 6.0$  level) 5 or more times per week was significantly higher ( $p < 0.001$ ) compared to those who rarely or never participated in vigorous activity. When habitual physical activity (estimated energy expenditure) was assessed by 1 year recall of activities, vigorous and non-vigorous levels of estimated energy expenditure (metabolic equivalent  $\geq 6.0$  and  $< 6.0$  respectively) were each positively and independently associated with insulin sensitivity. As participation in vigorous activities increased during the week the insulin sensitivity increased accordingly and the results were similar for subgroups of gender, ethnicity, and diabetes. These findings lend further support for the current recommendations of the 2005 Dietary Guidelines for Americans encouraging all U.S. adults to participate in at least 30 minutes

of moderate intensity physical activity on most days of the week.

In a controlled randomized study, Ronnema and associates (1986) also examined the effect of 4 months of physical exercise on the metabolic control in 25 patients with type 2 diabetes. Subjects were divided randomly into exercise (n=13) and control (n=12) groups. In the exercise group, plasma HgbA1c levels fell from 9.6 to 8.6% ( $p < 0.01$ ), while in the control group no changes occurred in any parameters of glucose metabolism. The response of plasma insulin to oral glucose increased significantly during the exercise period; however, patients with the poorest metabolic control initially were not able to improve their physical fitness and did not show significant improvement in metabolic control (Ronnema et al, 1986). The results support the evidence that physical exercise is beneficial for the glycemic control in individuals with mild and moderate type 2 diabetes, and that increased insulin response is at least one main mechanism of the action of exercise (Ronnema et al, 1986).

Improved glycemic control in individuals with type 2 diabetes was also noted in a randomly controlled study by Raz and associates (1994) and their findings support those reported by Ronnema et al (1986). The investigators studied the influence of moderate exercise training on parameters of glucose control in individuals with type 2 diabetes (Raz et al, 1994). Forty individuals aged  $56.6 \pm 6.6$  years were assigned randomly according to age and gender into exercise and control groups. The exercise group trained for 45 minutes, 3 times/week for 12 weeks, and the control group did not change their lifestyle. At the end of the study the exercise group had a significant reduction in plasma levels of HgbA1c ( $p < 0.05$ ) and triglycerides ( $p < 0.05$ ). The improvement in metabolic

control persisted significantly in individuals who continued to exercise at home during one year of follow up (Raz et al, 1994).

In a randomized control study Tessier and colleagues (2000) studied the impact of an aerobic physical exercise program in the treatment of a group of elderly patients with type 2 diabetes in relation to metabolic control, physical capacity, quality of life, and attitudes toward diabetes. This study differed from the previously mentioned studies as it targeted the elderly population. Patients were randomly assigned to an intervention (n=19) group that received an active physical training program or to a control (n=20) group who received instructions to continue with their usual activity regimen (Tessier et al, 2000). The following measurements were conducted at baseline and after 16 weeks for both groups: HgbA1c level, fructosamine, 3 hour oral glucose tolerance test, treadmill test, and questionnaire on quality of life and attitude toward diabetes. After the intervention, the experimental group showed a significant decrease of glucose excursion during the oral glucose tolerance test (area under the curve) and an increase in total time on the treadmill (Tessier et al, 2000).

Although physical activity is recommended as a basic treatment for individuals with diabetes, its long-term association with mortality was investigated by Wei and associates (2000) in a prospective cohort study. They evaluated the prospective association of cardiorespiratory fitness and physical inactivity with their primary outcome measure of all-cause mortality in 1,263 men of predominately non-Hispanic White ethnicity ( $50 \pm 10$  years of age) who were diagnosed with diabetes (Wei et al, 2000). These men received a thorough medical evaluation at the Cooper Clinic in Dallas, Texas between 1970 and 1993 and were followed for mortality up to December 31, 1994.

The average follow up was 12 years. After adjustment for baseline CVD, age, fasting plasma glucose, high cholesterol, overweight, current smoking, high blood pressure, and parental history of CVD, men in the low fitness group had an adjusted risk for all cause mortality of 2.1 compared with fit men. Men who reported being physically inactive had an adjusted risk for mortality that was 1.7 fold higher than that in men who reported being physically active. They concluded that low cardiorespiratory fitness and physical inactivity are independent predictors of all cause mortality in men with type 2 diabetes (Wei et al, 2000).

Meta-analyses. A meta-analysis completed by Boulé and colleagues (2001) reviewed the effects of structured exercise interventions in clinical trials of duration  $\geq 8$  weeks on plasma HgbA1c levels and body mass in people with type 2 diabetes. Twelve aerobic training studies and two resistance training studies were included (Boulé et al, 2001). The classes averaged 53 minutes/session, 3.4 sessions per week, for 15 weeks. The exercise and control groups did not differ at baseline in body weight or plasma HgbA1c. Post-intervention plasma HgbA1c levels were significantly lower ( $p < 0.01$ ) in exercise than control groups (7.65% vs. 8.31%); however, change in body weight was not significant (Boulé et al, 2001). Structured exercise programs had a statistically and clinically significant beneficial effect on glycemic control, which was not mediated primarily by weight loss. Although the individual trials on the effects of exercise in patients with type 2 diabetes have had partially conflicting results, this meta-analysis suggests that exercise training reduces plasma HgbA1c levels by approximately 0.66%, an amount that would be expected to reduce the risk of diabetic complications

significantly (Boulé et al, 2001).

Boulé and colleagues later undertook a meta-analysis that expanded on their previous analysis (2001), by looking at interrelationships among exercise volume, exercise intensity, change in cardiorespiratory fitness, and change in plasma HgbA1c levels (2003). This analysis was restricted to aerobic exercise studies in which  $VO_{2max}$  was either estimated from a maximal exercise test using a validated equation or directly measured (Boulé et al, 2003). Exercise volume during training ranged from 8.75-24.75 MET-hours/week (Boulé et al, 2003). MET-hours are units of exercise volume in which intensity in METs is multiplied by duration of the activity in hours (Sigal et al, 2004). Exercise intensities ranged from ~50% of  $VO_{2max}$  to > 75% of  $VO_{2max}$  (Boulé et al, 2003). Intensity of exercise is considered “moderate” when it is at 40-60% of  $VO_{2max}$  (~50-70% of maximum heart rate) and “vigorous” when it is at > 60% of  $VO_{2max}$  (>70% of maximum heart rate) (Sigal et al, 2004). The meta-analysis revealed that exercise intensity had the greatest effect on plasma HgbA1c levels (Boulé et al, 2003). Unfortunately, the analysis was limited by the fact that only one study (Mourier et al, 1997) featured a high intensity exercise program at 75% of  $VO_{2max}$ . This intensity might be hazardous for many previously sedentary people with type 2 diabetes (Sigal et al, 2004). The lower intensity activity affords a more comfortable level of exertion and enhances the likelihood of adherence, while lessening the likelihood of musculoskeletal injury and foot trauma, particularly when weight-bearing activity is recommended (Gordon, 1995).

Physical Activity Recommendations. Physical activity is a major therapeutic modality for type 2 diabetes; unfortunately, too often it is an underutilized therapy. Of

individuals with type 2 diabetes, 31% report no regular physical activity and another 38% report less than recommended levels of physical activity (Nelson et al, 2002). To improve glycemic control for individuals with type 2 diabetes the recommendation is to perform at least 150 minutes/week of moderate-intensity aerobic physical activity (40-60% of  $VO_{2max}$  or 50-70% of maximum heart rate) and/or at least 90 minutes/week of vigorous aerobic exercise (> 60% of  $VO_{2max}$  or > 70% of maximum heart rate) (Sigal et al, 2004). The effect on insulin sensitivity of a single bout of aerobic exercise lasts 24-72 hours, depending on the duration and intensity of the activity (Wallberg-Henriksson et al, 1998); therefore, physical activity should be distributed over at least 3 days/week and with no more than 2 consecutive days without physical activity (Sigal et al, 2004).

### Self-care Management

Diabetes self-management may be considered the foundation of the overall management of diabetes (Ruggiero et al, 1997). Once an appropriate medical regimen is determined (that includes a healthy diet and physical activity guidelines) and diabetes education is provided, the burden is on the individual to modify or maintain the complex set of behaviors needed to manage diabetes on a daily basis. Daily management of diabetes generally involves following a regular eating and exercise plan, self-testing blood glucose levels, and for many taking medication, and then implementing appropriate changes in the daily plan when necessary (Ruggiero et al, 1997). The goal of this combination of tasks is to maintain glucose levels within an acceptable range (Ruggiero et al, 1997). Goodall and Halford (1991) define self-management as a set of skilled behaviors engaged in to manage one's own illness. The process of teaching individuals

to manage their diabetes has been an important part of clinical management since the 1930s (Bartlett, 1986). To highlight the importance of self-management in the treatment of type 2 diabetes, the Diabetes Control and Complications trial will be reviewed.

Diabetes Control and Complications Trial (DCCT). The results of the DCCT underscore the importance of behavior in the management of diabetes (DCCT, 1993). In this 29 center controlled clinical trial conducted between 1982 and 1993, the effects of intensive diabetes therapy on long-term complications in type 1 diabetes were studied (DCCT, 1993). The therapy was aimed at achieving glycemic levels as close to the non-diabetic range as safely possible. Individuals who regularly followed tasks involved in intensive management programs achieved better short and long-term health; such as delaying the onset and slowing the progression of diabetic retinopathy, nephropathy, and neuropathy (DCCT, 1993).

Self-management practices of individuals with type 1 or type 2 diabetes have also been studied by Sadur and associates (1999). This study involved a randomized, controlled trial among patients of Kaiser Permanente in Pleasanton, CA (Sadur et al, 1999). Subjects 16-75 years of age, either had poor glycemic control ( $HgbA1c > 8.5\%$ ) or no plasma  $HgbA1c$  test performed during the previous year. Intervention subjects ( $n=97$ ) received multidisciplinary outpatient diabetes care management delivered by a diabetes nurse educator, a nutritionist, a psychologist, and a pharmacist in cluster visit settings of 10-18 patients per month for 6 months, while control subjects ( $n=88$ ) received usual care by primary care physicians. Outcomes included change in plasma  $HgbA1c$  levels from baseline; self-reported changes in self-care practices, self-efficacy, and

satisfaction; and utilization of inpatient and outpatient health care. After the intervention, plasma HgbA1c levels declined significantly ( $p < 0.001$ ) by 1.3% in the intervention subjects versus 0.2% in the control subjects. Several self-care practices and measures of self-efficacy improved significantly in the intervention group such as number of times/day blood glucose was monitored ( $p < 0.0001$ ), balancing diet to keep blood glucose in control ( $p = 0.003$ ), and recognizing and treating low blood glucose ( $p = 0.03$ ) (Sadur et al, 1999).

From the Kaiser study it is clear that self-care practices are tied to improvement in glycemic control. In a program developed specifically for individuals with diabetes, Healthy Changes for Living with Diabetes, emphasizes self-management in its curriculum (NCOA, 2004). The program depends less on learning facts about a particular condition and more on learning how to set reasonable goals, problem solve, and having a source of peer support. Research suggests that goal setting, problem solving, and peer support are important components in the development of self-management skills (Clark et al, 1991; Lorig et al, 1999). The National Council on Aging (NCOA), which disseminates information to aging network providers across the nation, selected Portland, Oregon as one of four cities to test model health promotion and wellness programs. A steering committee of senior service providers, health care providers, diabetes and geriatric experts, under the leadership of the Providence Center on Aging, developed the Healthy Changes project from topics designated by the NCOA. Healthy Changes for Living with Diabetes is one component of the Model Programs Project of the NCOA (2004). The steering committee used evidence-based findings to



design the model. Deborah Toobert, PhD with Oregon Research Institute in Eugene evaluated Healthy Changes during a 6 month pilot phase of the program. That evaluation showed that 81% of individuals involved in the program achieved their health goals, including losing weight, exercising more, eating a healthier diet, and utilizing more community resources (Toobert and Strycker, 2004). Members of the Providence Center on Aging steering committee developed the tool used to measure these outcomes using validated questions from similar research projects.

Self-management training for Hispanic individuals with diabetes may be beneficial as well. According to a review completed by Jovanovic and Harrison (2004), the unfavorable consequences of diabetes in Hispanic individuals may be due in part to differences in self-management. The key to improving outcomes in the Hispanic population lies in enhancement of communication to overcome barriers to self-care. It is important to better understand the cultural milieu in minority communities to enhance involvement of Hispanic individuals with diabetes in their own management (Jovanovic and Harrison, 2004).

Hispanic Population. Two studies that included diabetes self-management training in the Hispanic population were reviewed (Brown and Hanis, 1995 and 1999). The purpose of a pilot study conducted by Brown and Hanis (1995) was to determine the feasibility of providing a diabetes patient education and group support intervention that was aimed at improving the health of Mexican-Americans and that was directed by a Mexican-American nurse, RD, and community worker. In a rural Texas-Mexico border community (Starr County), participants with diabetes were randomly selected to participate in the intervention, and a family member of each subject participated as a

support person. The intervention involved 8 weekly, 2 hour education sessions and one 2 hour support group session with instruction on nutrition, exercise, blood glucose self-monitoring, and other diabetes self-management topics identified by the National Diabetes Advisory Board. After the intervention, statistically significant ( $p < 0.05$ ) improvements were observed in diabetes knowledge, fasting blood sugar, and HgbA1c levels (Brown and Hanis, 1995). The mean plasma HgbA1c and fasting glucose levels were reduced by 2.4% and 73 mg/dL, respectively; however, due to the small sample size ( $n=5$ ) these data must be interpreted cautiously (Brown and Hanis, 1995).

From this pilot study Brown and Hanis further tested this culturally competent intervention in Starr County with a randomized, controlled clinical investigation (1999) (Table 2.3). During the course of the study, 247 participants with type 2 diabetes and their support partner were enrolled, 125 into the treatment group and 122 into wait listed control groups (Brown and Hanis, 1999). The majority of participants were female (64%) and on average, in their mid-fifties (mean age=54 years). The intervention which included self-care as a key component expanded on the 8 week version in the pilot study and included 12 weekly educational sessions providing critical diabetes self-care information; 14 biweekly support group sessions were held subsequently, with monthly sessions during the last 3 months all over a 1 year time span. Each of the 26 sessions was 2 hours in length. The primary study outcomes were HgbA1c and fasting blood glucose levels. At 6 months fasting blood glucose levels had declined significantly in the treatment group (a reduction of 27.9 mg/dL) compared with an increase of 8.4 mg/dL in the control group. By 12 months, the treatment group experienced an 18.9 mg/dL

reduction in fasting blood glucose levels compared with a 3.9 mg/dL increase in the control group. HgbA1c decreased by 1.7 percentage points in the treatment group at 12 months compared with an increase of 0.3 percentage points in the control group. One draw back to this study is that there was a noticeable drop in attendance at 13 weeks when the focus of the intervention changed from educational sessions to support group sessions, and by year's end attendance had declined by 50% (Brown and Hanis, 1999).

Based on the results of the Starr County diabetes self-management study discussed above, Brown and colleagues (2005) developed a less intensive “compressed” intervention involving 22 contact hours over 12 months as opposed to the original “extended” intervention involving 52 contact hours over 12 months. The objective of this study was to compare 2 diabetes self-management interventions designed for Mexican-Americans that were both culturally competent regarding language, diet, social emphasis, family participation, and incorporating cultural beliefs; however, they differed in total number of contact hours that were provided over the year long time frame (Brown et al, 2005). The extended intervention was compressed into fewer sessions; thus, providing more information during each group meeting. Another difference was the reduced number of support group sessions, which decreased from 14 to 3 sessions. A total of 216 individuals between 35 and 70 years of age with type 2 diabetes were recruited. Participants were similar to those in their previous studies, predominately female, obese, ~50 years of age on average, and in poor metabolic control. Individuals with diabetes and their support partner were randomly assigned to either the compressed (n=114) or extended (n=102) intervention. Three primary clinical outcomes were reported: HgbA1c, fasting blood glucose, and diabetes knowledge; however, no significant differences

between programs were found for any of the outcomes (Brown et al, 2005). Both interventions were effective in significantly lowering HgbA1c ( $p \leq 0.05$ ), fasting blood glucose ( $p = 0.05$ ), and diabetes knowledge ( $p = 0.001$ ). For individuals who attended  $\geq 50\%$  of the intervention, the change in HgbA1c from baseline to 12 months post-intervention was -0.6 percentage points for the compressed group and -1.7 percentage points for the extended group. A “dosage effect” of attendance was detected with the largest HgbA1c reductions achieved by those who attended more of the extended intervention. Although the percentage change in HgbA1c seems small, for every 1 percentage point decrease in HgbA1c there is a 35% reduction in the risk of microvascular complication, a 25% reduction in diabetes related deaths, a 7% reduction in all cause mortality, and an 18% reduction in combined fatal and nonfatal myocardial infarction (ADA, 2001).

Along the same lines as the Brown studies, Banister and associates (2004) (Table 2.3), investigated the effects of a diabetes self-management program directed toward individuals with type 2 diabetes. Clinical outcomes included BMI, diabetes medication use, and HgbA1c (Banister et al, 2004). Education was provided to 70 participants in a 4 hour monthly group class, followed by  $\geq 1$  individual dietitian consultation, and monthly support meetings over a 1 year time frame. Mean hours of attending all 3 components were  $6.5 \pm 3$ . Most participants were Hispanic ( $n=39$ ) or African American ( $n=16$ ) with a mean age of  $49 \pm 10$  years and mean BMI of  $34 \pm 9$  kg/m<sup>2</sup> (Banister et al, 2004). At the completion of the intervention, 27% attained the HgbA1c goal of  $\leq 7\%$  and mean plasma HgbA1c levels improved significantly ( $p < 0.001$ ) from  $9.7 \pm 2.4\%$  to  $8.2 \pm 2.0\%$ ,

representing a 15% decrease. In addition, 61% of participants maintained or reduced their medication regimens. Those participants who significantly ( $p = 0.013$ ) discontinued or decreased the dose of their diabetes medications had the most hours of follow up education. Although the participants in this study did not lose weight, they did not experience weight gain, which is typical with sulfonylurea or insulin treatment (Banister et al, 2004).

Experimental Research. Hispanic individuals with chronic disease were studied in a randomized community based outcome trial conducted by Lorig et al (2003). The researchers evaluated the health and utilization outcomes of a community based 6 week program, Tomando Control de su Salud (Taking Control of Your Health), which was offered 2 ½ hours/week to Spanish speaking Hispanics with heart disease, lung disease, or type 2 diabetes (Lorig et al, 2003). The basic premise of the program consisted of building the participants confidence to be able to self-manage their health. Specifically, Tomando Control de su Salud (Tomando) is a Spanish chronic disease self-management program. Altogether 551 individuals agreed to participate in the randomized, controlled test of the program and were followed for a year. Of these 551 individuals, 327 were randomized to intervention and 224 served as usual care control subjects. After 4 months, this clinical trial of 327 participants demonstrated improved self-reported health status, health behavior (i.e., exercise, communication with their physician, and mental stress management), self-efficacy, and fewer emergency room visits as compared with usual care control subjects (Lorig et al, 2003). At 1 year, the improvements observed at 4 months were maintained and were statistically significant ( $p < 0.0001$ ) from baseline condition; with the exception of number of emergency room visits which was significant

at the  $p = 0.01$  level (Lorig et al, 2003).

Meta-analysis. To understand the extent to which self-management in diabetes has been studied, a total of 72 studies were identified by Norris and associates (2001) in a meta-analysis on the effectiveness of self-management training in type 2 diabetes.

Studies were original articles reporting the results of randomized controlled trials of the effectiveness of self-management training in individuals with type 2 diabetes. Positive effects of self-management training on knowledge, frequency, and accuracy of self-monitoring of blood glucose, glycemic control, and self-reported dietary habits were shown in studies with short follow up of  $< 6$  months. The conclusion of the meta-analysis indicated that the objectives for ideal self-management interventions in diabetes should include the following:

- Behavioral interventions must be practical and feasible in a variety of settings.
- The intervention must be effective for long-term important physiological outcomes, behavioral end points, and quality of life.
- Patients must be satisfied.
- The intervention must be relatively low-cost and cost effective.

According to Norris and colleagues (2001), there are some well-designed and executed studies that support the effectiveness of self-management training for individuals with type 2 diabetes, particularly in the short-term. The challenge, according to Norris et al (2001), is to expand upon this current knowledge to achieve all of the objectives of ideal self-management. They also concluded that further research is needed in diverse populations and settings.

In summary, due to limited self-management studies in the Hispanic population

further research is needed to assess the effectiveness of self-management interventions on sustained glycemic control in this particular population. The Hispanic population is not only at higher risk for having diabetes, but also are more likely to develop serious diabetes complications that could lead to disability or death. The challenge for educators and clinicians is to provide the ethnic population with the best tools and empowering them with the knowledge they need to help control their diabetes and prevent its complications.

### Social Support

As outlined and discussed in this review, good nutrition, exercise, and a strong commitment to self-management by the individual with diabetes is essential for treating the disease. Following recommended treatment guidelines often necessitates making changes in everyday lifestyle patterns, which makes the social world of a person living with diabetes an important factor in this process.

Diabetes has the potential to impact the entire family. Children of individuals with diabetes are at increased risk of developing the disease, probably due to an interaction of genetic and environmental factors. Even spouses of persons with diabetes have an increased risk of developing diabetes, presumably due to common environmental influences (Hanis et al, 1983).

Due to the importance of family in the Hispanic culture, educating the family unit about the illness and encouraging family members to understand and support the patient's treatment efforts could greatly enhance treatment adherence. Many decisions in the Hispanic family, including individual health care, are made by the family (Oomen et al,

1999). Therefore, educating the family about the illness provides them with information that may help them to make appropriate treatment decisions.

Educating the family unit about the illness serves another purpose as oftentimes family members provide caregiving activities for the individual with diabetes. Caregiving activities of spouses and adult children for adults with diabetes are recognized; however, little attention has been given to the possible caregiving activities of children (Jacobson and Wood, 2004). In an exploratory descriptive study, 51 diverse adults with diabetes from 9 clinics in 3 states completed a survey in English or Spanish about themselves and their child caregivers. The purpose of the study was to determine the occurrence of child caregivers among adults with diabetes and the type of assistance they provide. The results indicated that some children were making major contributions to the adults' care often with little or no education related to the services. The most frequent services provided by children for their adult family member were providing juice or food during periods of hypoglycemia, assistance with meal planning or preparation, staying with the adult at night or when ill, and promoting physical activity. Six of the 16 Hispanic children served as interpreters at clinic visits. The findings of this study suggest that the occurrence of child caregiving for adults with diabetes is high enough and consistent enough across racial and ethnic groups that diabetes educators should consider the possibility that children are involved in caregiving in families where an adult under age 60 has diabetes, this possibility is especially likely for Hispanic families (Jacobson and Wood, 2004).

Social support has been found to be a relevant factor in diabetes self-management;



however, it has not been extensively explored within the Hispanic community (Gleeson-Kreig et al, 2002). Gleeson-Kreig and colleagues (2002) conducted a cross-sectional study with 95 (30 male and 65 female) insulin requiring Hispanic adults to explore the composition of the support network, the type of assistance needed, the degree of satisfaction with support received, and the relationship between social support and diabetes self-management. Participants were visited in their homes by trained bilingual and bicultural interviewers, who administered instruments in Spanish that measure social support, diabetes self-efficacy, and demographic variables. Family members were found to be the greatest source of expected assistance for this sample, with 94% stating that they would expect a family member to be available to help. The greatest need for assistance was associated with interactions that involved speaking English or with transportation. The assistance offered in these areas was viewed as highly satisfactory but help available for personal care, diabetes self-care, and financial assistance was less satisfactory. Interestingly enough, social support was not strongly related to diabetes self-management (Gleeson-Kreig et al, 2002).

In the previous study family members were not educated about diabetes; however, in a study where education was provided the outcome results were more positive. Gerstle and associates (2001) investigated the influence of family adaptation on glycemic control in women with type 2 diabetes mellitus who had been provided with nutrition education as part of a 2 ½ year ethnography. Data analysis included quantitative data (self-monitored fasting blood glucose and food records), and descriptive data (observations, transcribed audio recordings, and written field notes) from families of 5 (3 Italian-Americans, 1 Irish-American, 1 African American) New York suburban women (Gerstle

et al, 2001). Among the women with improved glycemic control, the family and home routines had changed. The social context of the women's daily lives influenced their glycemic control; in other words, family members other than the women with diabetes took on new "hospital roles and routines". The researchers concluded that nutrition education should be directed toward assessing existing family social support and to help organize and supplement this support to ensure the successful completion of the diabetes self-management tasks (Gerstle et al, 2001). The small sample size however limits the generalization of the findings.

Studies have linked social support positively to diabetes health status, success with complying with treatment regimens, and better self-care (Gleeson-Kreig et al, 2002). A meta-analysis conducted by Brown and Hedges (1994) demonstrated a direct positive relationship between perceived social support and improved metabolic control. However, further studies are warranted that clearly explicate the role of social support for Hispanic individuals with diabetes.

In conclusion, the goal of treatment in type 2 diabetes is to achieve and maintain near normal blood glucose levels and optimal lipid/blood pressure levels in order to prevent or delay complications associated with the disease. Proper nutrition, exercise, daily management of the disease, and social support are all critical factors in the treatment of diabetes; however, they have not been extensively studied in the Hispanic population.

## **HISPANIC HEALTH PROMOTION PROGRAMS**

Given the fact that the Hispanic population is at particularly high risk for type 2

diabetes, efforts are being made to educate this segment of the population about the disease in an effort to reduce the disability and death associated with diabetes and its complications. In this section, three programs that offer a unique and different approach to educating the Hispanic population about preventing and/or managing chronic disease will be highlighted. Research has demonstrated that certain culturally relevant practices contribute to the success of health promotion projects in the Hispanic/Latino community (Corkery et al, 1997). Each program discussed below has incorporated culturally sensitive education practices into their programs in an effort to more effectively communicate to the Hispanic population the ramifications of chronic disease.

#### Paso a Paso

To help Hispanic and Latino Americans prevent diabetes, the National Diabetes Education Program (NDEP), a joint effort of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), launched the *Prevenamos la diabetes tipo 2. Paso a Paso* (let's prevent type 2 diabetes: step by step) campaign to help spread the message of hope that diabetes can be prevented to the millions of at risk Hispanics (NIH, 2004). The campaign includes the following components:

- National radio public service messages on Spanish language radio stations across the country.
- Printed public service announcements that encourage Hispanics to prevent diabetes.
- A recipe and meal planner booklet featuring healthier twists on traditional Latino recipes.
- New education materials on diabetes prevention.

### Tomando Control de su Salud (Tomando)

The Tomando program was developed by the Department of Medicine in the School of Medicine at Stanford University (SPERC, 1999). The program is being used in community settings such as churches, senior centers, libraries, and clinics for Spanish speaking individuals with chronic health problems; including, heart disease, arthritis, and diabetes. All workshops are given in Spanish by trained leaders that have been certified to teach the class after a 4 ½ day training session with Stanford University. The program includes the following subjects: 1) techniques to deal with problems such as frustration, fatigue, pain, and isolation, 2) appropriate exercise for maintaining and improving strength, flexibility, and endurance, 3) appropriate use of medications, 4) healthy eating, 5) communicating effectively with family, friends, and health professionals, 6) appropriate use of the health care system, and 7) how to evaluate new treatments. The process in which the program is taught makes it effective. Classes are participative, where mutual support and success build the participants confidence in their ability to manage their health and maintain active and fulfilling lives.

### Border Health Strategic Initiative (BHSI)

To confront the threat of diabetes on the U.S.-Mexico border, representatives from Yuma and Santa Cruz counties located in Arizona joined with the University of Arizona in October 2000 to develop and test a comprehensive and sustainable model for community oriented diabetes prevention and control (Ingram et al, 2005). Both Yuma and Santa Cruz counties are rural and more than 90% Hispanic. Although diabetes prevention was an important focus for the project, patients diagnosed with diabetes, and

their families were also targeted. The project included the following program components: patient self-management, quality of care improvement, patient/family prevention and support, community nutrition and exercise, and school health policy. The patient and family components will be described in more detail in the following pages.

The patient component of the BHSI used community health workers to provide culturally relevant diabetes education in the 2 counties. Community health workers are often referred to as *Promotoras*, from a Spanish term for lay community educators. They are trusted community members that provide informal community based health related services and establish vital cross-cultural links between health providers and the community (Zuvekas et al, 1999). Community health workers function as teachers, peer counselors, and advocates of grassroots change in their own communities (generally under the supervision of a nurse or social worker). They are effective educators because they relate better to their peers than do outsiders and provide culturally sensitive instruction that facilitates community self-development.

The curriculum for the BHSI diabetes education program was developed by the Certified Diabetes Educator (CDE) working in one of the counties using the American Diabetes Association (ADA) Standards of Care (Ingram et al, 2005). The curriculum included 2 hour classes held once a week over a 5 week period. The sessions included the following topics: 1) understanding diabetes, 2) meal planning, 3) avoiding complications and maintaining health, 4) monitoring, medications, and movement, and 5) foot/eye clinics. Participants were encouraged to bring family members.

Assessment of the effectiveness of the program was done using a quantitative instrument that was developed by the program partners in both Yuma and Santa Cruz

counties. This questionnaire was given prior to initiation in the program and 6 months after the last class was finished. Health outcomes included random blood glucose, blood pressure, body weight, and HgbA1c. Measurements of these outcomes were taken pre and post-program and 6 months after the last class, with the exception of HgbA1c which was only measured in 1 county twice (before class and 6 months after the last class was finished). Results revealed there was a significant decrease ( $p < 0.001$ ) in the average random blood glucose measurement among participants in both counties between pre and post-program data, but no significant changes in health outcomes at 6 month follow up. When HgbA1c was measured, there was a significant decrease ( $p < 0.001$ ) in levels among those who initiated the program with a HgbA1c  $> 6.9\%$ . Both counties also had significant changes in exercising regularly and foot care ( $p < 0.05$ ); and in one county, the percentage of individuals following a diabetes diet increased significantly ( $p < 0.001$ ). Both counties used findings to pursue and secure additional funding to sustain services.

In the patient component discussed above, family influence was not evaluated; however, the objectives of the family component of the BHSI were to: 1) enhance family members social support of patients with diabetes, and 2) increase the range of primary prevention behaviors associated with diabetes in family members of patients with diabetes (Teufel-Shone et al, 2005). Community and university partners designed a culturally appropriate 12 week program addressing family food choices and physical activity, behavior change, communication, and support behaviors. Seventy-two families, (n=249) including children and grandchildren participated. Pre and post-intervention

questionnaires completed by adults (n=116) indicated a significant increase ( $p < 0.01$ ) in knowledge for eight diabetes risk factors, and a significant increase ( $p < 0.001$ ) in family efficacy to change food and activity behaviors (Teufel-Shone et al, 2005). In addition, significant patterns of change occurred for the following: 1) frequency of sweetened drink consumption decreased significantly ( $p < 0.001$ ), 2) a significant increase ( $p = 0.002$ ) in family members participating together in physical activity, and 3) a significant increase ( $p = 0.01$ ) in participants reporting that family members help and support each other (Teufel-Shone et al, 2005).

In conclusion, diabetes disproportionately affects Hispanics in the U.S. The aforementioned programs were developed to help educate the Hispanic population on the importance of reducing modifiable risk factors for chronic disease, diabetes in particular. The 4<sup>th</sup> and last section that follows will examine what is being done in the state of Oregon to help reduce the burden of diabetes in the general population of which Hispanics/Latinos are the largest growing ethnic group.

## **OREGON'S ACTION PLAN FOR DIABETES**

To evaluate how well the state of Oregon is doing in reducing the burden of diabetes the Oregon Diabetes Prevention and Control Program (ODPCP) recently provided a 2005 Report Card to the members of the Oregon Diabetes Coalition, which is comprised of 5 core organizations along with staff from health care and social services agencies, individuals living with diabetes, and concerned citizens and professionals. The 5 organizations include: Office of Medical Assistance Programs (OMAP), Oregon's Medical Professional Review Organization (OMPRO), American Diabetes Association

serving Oregon and Southwest Washington (ADA), Department of Human Services, Health Services, Oregon Diabetes Prevention and Control Program (ODPCP), and Oregon Diabetes Educators (ODE). The report card (DHS, 2005 Report Card) serves as a means of tracking progress in the Oregon Diabetes Coalition's *Action Plan For Diabetes*. The plan describes goals, objectives, and strategies for reducing the burden of diabetes in Oregon. The report card is also available to health care professionals for policy making and program planning in the area of diabetes.

Oregon Department of Health Services data (2005) show statewide efforts are making a difference in the following areas:

- Diabetes related preventive services among adult Oregonians has improved.
- Oregonians with diabetes report that they are receiving and understanding self-care education from their doctor or other health provider.
- There are some favorable upward trends in reported beneficial self-management behaviors among Oregonians with diabetes.

Despite these positive changes, Oregon continues to face ongoing challenges in the following areas:

- Only 20% of adult Oregonians with diabetes report receiving all five of the following recommended preventive services-annual foot exam, eye exam, and flu shot, biannual HgbA1c test, and ever having a pneumonia vaccine.
- Among adult Oregonians at higher risk for diabetes, close to half were not at all worried about getting diabetes in the future.
- Getting regular physical activity and following a recommended eating plan continue to be difficult self-care tasks for those with diabetes.

A number of objectives have been outlined to help overcome these challenges.

One objective is to increase community partnerships that result in screening, diagnosis,

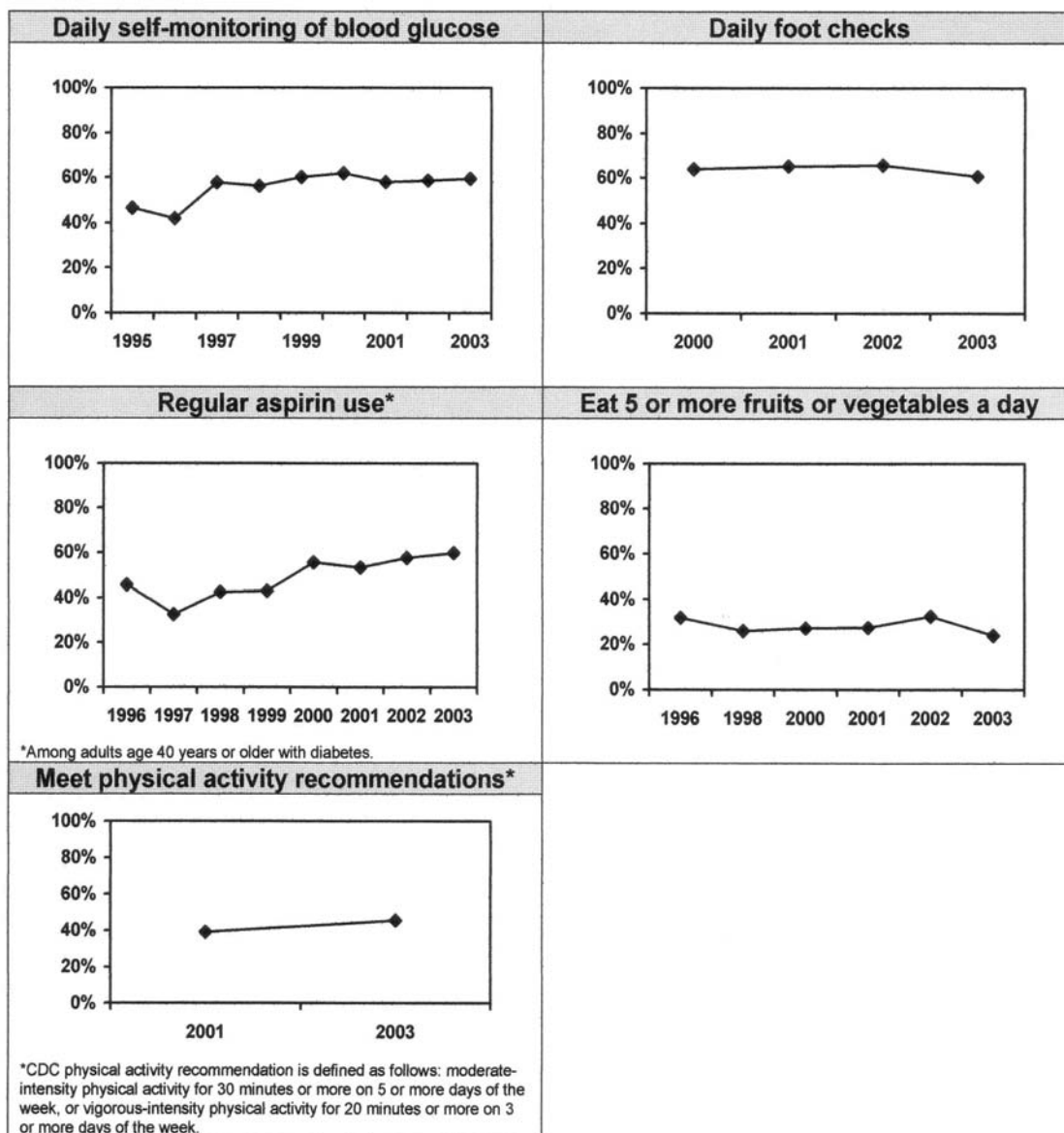


education, and treatment activities. Another objective is to increase the number of counties and underserved populations in Oregon with an organized system of diabetes education. And last, there is an objective to increase the percentage of Oregonians with diabetes who carry out self-management behaviors to reduce chronic complications.

Figure 2.1 shows trends in the percentage of Oregonian adults with diabetes engaging in a number of important self-management activities. As can be seen, there is still room for improvement.

In order to better understand the resources and barriers that exist for Hispanics/Latinos with diabetes in Oregon, the ODPCP conducted interviews and focus groups in 2001 in three Oregon communities with sizeable Hispanic/Latino populations (Umatilla, Deschutes, and Jackson counties). Hispanic/Latino community members and leaders were interviewed and they verified the need for more education regarding ways to prevent and manage diabetes. In each focus group, participants ranked diabetes as one of the three most serious diseases affecting Hispanics/Latinos, along with cancer and heart disease. Participants stated there is very little accurate information about diabetes in their communities and there are many myths and misconceptions about the disease. This lack of accurate information regarding diabetes creates a need for a community based intervention that will fill those gaps.

To help address the problem of health disparities and the rising occurrence of diabetes, Oregon State University (OSU) partnered with the State of Oregon to complete a pilot diabetes intervention study in 2 Oregon counties. This intervention provided culturally relevant diabetes education in the areas of nutrition, physical activity, and



Source: DHS, 2005 Report Card

**Figure 2.1 Percent of Oregonian adults with diabetes engaging in self-management activities**

self-care to Hispanics with diabetes and their support person. The classes were taught in Spanish by bilingual, culturally sensitive community health workers, with current knowledge of diabetes in the Hispanic population. The university's role is to evaluate

the effectiveness of this program for the State of Oregon. Results of this pilot project will assist the State of Oregon in learning if culturally appropriate, family oriented diabetes interventions are successful in the Hispanic community. If successful, this pilot project has the potential of being refined and developed into a statewide program.

In summary, the incidence of type 2 diabetes has increased in the U.S. and worldwide during the last decades, despite the development of effective drug therapy and improved clinical diagnoses. Type 2 diabetes is one of the major causes of disability and death due to the complications accompanying this disease and it disproportionately affects the Hispanic population. In many individuals, type 2 diabetes is likely to evolve from a combination of genetic and environmental factors, which together, lead to a progressive alteration in glucose homeostasis caused mainly by defects at 3 major sites: altered insulin secretion from the beta cell, elevated hepatic glucose production due to decreased insulin sensitivity in the liver, and diminished peripheral glucose utilization due to insulin resistance in skeletal muscle (Wallberg-Henriksson et al, 1998). In some cases, environmental factors such as inactivity and obesity are more important for the manifestation of the disease.

To improve glucose homeostasis self-care management, including physical activity and proper diet, is critical in treating diabetes. However despite this knowledge, 31% of individuals with type 2 diabetes report no regular physical activity and another 38% report less than recommended levels of physical activity. In addition, recent surveys in the U.S. have shown that many persons with type 2 diabetes do not follow dietary recommendations set by the American Diabetes Association for the treatment of the disease. For the well-being of individuals that are at risk for diabetes or have already

been diagnosed with the disease the development of effective intervention strategies is essential in order to properly treat and reduce the incidence of type 2 diabetes and its resulting complications.

Research examining interventions that have been developed specifically for the Hispanic population that include nutrition, physical activity, self-care, and the inclusion of a support person has not been fully examined. The outcome variables in the study completed by Lemon and colleagues (2004) more closely match the variables that will be looked at in this study (HgbA1c, fasting plasma glucose, CHD risk, diet, and exercise); however, the study participants were non-Hispanic, the intervention focused mainly on nutrition, and the study did not look at change in insulin resistance. On the other hand, the intervention program used by Brown and Hanis (1999) more closely resembles the intervention that will be used in this study; however, the outcome variables did not include diet, exercise, and change in insulin resistance. Therefore, this study will expand on what has already been investigated and should add greatly to the diabetes intervention research for the Hispanic population.

## CHAPTER 3 - METHODS

### EXPERIMENTAL DESIGN

A diabetes educational intervention program, consisting of a total of 20-25 hours, focusing on nutrition, physical activity, and self-care was taught by community health workers in 2 separate counties in Oregon. The target audience was Hispanic individuals with diabetes living in Multnomah (MC) and Hood River (HRC) counties of Oregon. The counties were allowed to pick which diabetes intervention program to implement based on their ability to deliver the program. Multnomah County chose Tomando Control de su Salud educational program (Lorig et al, 2003), and the Spanish version of the Meals Made Easy for Diabetes educational program “Platos Saludables”, which was developed through a collaborative process led by Carol Walsh, RD, MS, CDE, in 2003 for the Oregon Department of Human Services, Health Services (personal communication). Hood River county chose the Healthy Changes for Living with Diabetes educational program (NCOA, 2004). Table 3.1 outlines the basic overview of

**Table 3.1 Experimental design**

County	Pre-test	Educational Strategy	Post-test
Multnomah	n=20 participants with diabetes n=20 support participants	6-10 week intervention*, meeting 1-2 times/week, 2 ½ hrs/session for a total of ~25 hrs	n=20 participants with diabetes n=20 support participants
Hood River	n=20 participants with diabetes n=20 support participants	10 week intervention **, meeting 1 time/week, 2 hrs/session for a total of ~20 hrs	n=20 participants with diabetes n=20 support participants

\*Tomando Control de su Salud (Lorig et al, 2003) and Platos Saludables programs

\*\* Healthy Changes for Living with Diabetes program (NCOA, 2004)

the experimental design. Each site was to recruit 20 participants with diabetes and 20 support participants. The program was taught in Spanish by community health workers.

### County Selection

All local county health departments in Oregon were eligible to apply for funding to the ODPCP, at the Department of Human Services, Health Services (DHS) based on requirements established by the CDC. Preference was given to those counties with at least 5% of the county population as Hispanic. Seven counties submitted applications to the ODPCP at the DHS. A committee was established to help in the selection process that consisted of individuals from: Health Services and other DHS agencies, the Conference of Local Health Officials (CLHO) Chronic Disease Committee, the Oregon Diabetes Coalition, and Oregon State University. Every member on the committee scored each application according to established criteria set up by the ODPCP and the CDC. The group then met to discuss their scores and provide input as to which applications were most suited for the funding. These recommendations were then given to the ODPCP for the final decision. Multnomah and Hood River counties were awarded the grants. Using these two sites provided an opportunity to include participants from both an urban (Portland) and rural (Hood River) setting.

### Recruitment

Participants were recruited from MC in Portland and HRC. Recruitment was done with the assistance of staff from each of the participating counties in Oregon. Multnomah County recruited participants from Multnomah County Health Department clinics, especially those serving a high percentage of Hispanic patients such as La Clinica

de Buena Salud, East County Clinic, and North Portland Clinic. In Hood River County, participants were recruited from La Clinica del Carino Family Health Center and from Nuestra Comunidad Sana, a private, non-profit community based organization, through its diabetes outreach project.

Potential volunteers with diabetes responded by telephone or in person to flyers posted in the recruitment sites (Appendix 6). A brief interview (Appendix 7) was conducted by the contact person from each county to determine if the respondent was Hispanic, 19 years or older, diagnosed with diabetes, and would be able to recruit a support person(s) who would come with them to the education classes. If the individual with diabetes and their support person met the criteria and were interested in participating they had a detailed explanation of the study provided by the contact person from each county and signed an informed consent document (Appendices 8 and 9) before participating. If the social support person also had diabetes, they were recruited as part of the diabetic population. This study was approved by the Oregon State University Institutional Review Board (IRB) and all materials were translated into Spanish.

### Participant Population

Male and female Hispanics diagnosed with diabetes, ages 19 and older were recruited for this study from 2 locations (Multnomah and Hood River counties). In addition, each person with diabetes was to recruit one support person(s), who was at least 19 years or older. The support participant was expected to attend each class session with their partner who has diabetes. The role of the support participant was to help their partner with diabetes make healthy lifestyle changes. The participating population was

Spanish speaking with low literacy skills, all classes were taught in Spanish.

Acculturation of the participants was also examined. After completion of the intervention program a facilitator from each county was to fill out an acculturation questionnaire (Appendix 10) that had been adapted from the 4-item language scale developed for Hispanics (Marin et al, 1987). The questionnaire provided, in general, how acculturated the whole class was and if there were any differences between the 2 counties. In a study conducted by Suris and associates (1998) the more acculturated Mexican-American subjects reported greater readiness to change health behaviors.

#### Materials

The recruitment flyers, telephone script, informed consent documents, and questionnaires were translated into Spanish by a Spanish/English translator. All the forms and documents that required translating were reviewed by a Spanish speaking community health worker in each county to ensure the age-level of the language used would be appropriate for the population. These same community health workers also reviewed the translated materials for clarity.

#### Incentives

In order to encourage classroom attendance snacks were offered at each class in both counties. In addition, HRC had a drawing each week and 1 participant won a prize such as a gift certificate to a local business in the community. Multnomah County provided a small gift to each participant at every class; ie, cookbooks, water bottles, etc. They also provided a monetary allowance for daycare for those participants with small



children.

### Intervention

Based on the request for proposals developed by the ODPCP, at the DHS, each county selected one of two ways to implement the pilot diabetes educational intervention to the diabetic Hispanic target population in their community. Both education programs focused on lifestyle changes aimed at improving diet, physical activity, and self-care, and were consistent with the primary outcome variables in this study. The educational programs offered in each county are listed in the following table.

**Table 3.2 Educational programs in each county**

Option 1 – Multnomah County	Option 2 – Hood River County
<p>Tomando Control de su Salud (for self-management) (Lorig et al, 2003)</p> <ul style="list-style-type: none"> <li>• Setting goals</li> <li>• Managing symptoms</li> <li>• Family relations and decisions regarding treatment</li> <li>• Exercise</li> </ul> <p>Platos Saludables (for meal planning)</p> <ul style="list-style-type: none"> <li>• Meals and snacks using the plate method</li> <li>• Modifying recipes for less saturated fat and more fiber from fruit, vegetables, and whole grains</li> <li>• Cooking demonstrations</li> <li>• Smart shopping (grocery store tour)</li> </ul>	<p>Healthy Changes for Living with Diabetes (for self-management and meal planning) (NCOA, 2004)</p> <ul style="list-style-type: none"> <li>• Setting goals and developing a plan for making changes</li> <li>• Healthy food choices; i.e., choose fiber rich fruits, vegetables, and whole grains often, and limit foods that are high in fat, saturated fat, and cholesterol</li> <li>• Meal planning</li> <li>• Principles of physical activity</li> <li>• Support from family, friends, and community resources</li> <li>• Self-management</li> <li>• Smart shopping (grocery store tour)</li> </ul>
<p>Walking program</p> <ul style="list-style-type: none"> <li>• The use of pedometers and a walking journal for physical activity</li> </ul>	<p>Walking program</p> <ul style="list-style-type: none"> <li>• The use of pedometers and a walking journal for physical activity</li> </ul>

Multnomah County implemented the Tomando Control de su Salud program (Lorig et al, 2003). This is a community based program for Spanish speaking Hispanics with chronic disease. Stanford University School of Medicine developed this program that incorporates subjects important to successful self-care. Multnomah County also implemented Platos Saludables, which was developed through a collaborative process, that was led by Carol Walsh, RD, MS, CDE (Corvallis, OR). The evaluation of the English version of Platos Saludables was conducted by the ODPCP and OSU graduate student, Jeri Greenberg (Greenberg, 2005). This program is supported by the ODPCP and the OSU Extension Service. This meal planning program is intended to provide individuals with diabetes and their support person with basic principles and guidelines for healthy meal planning using hands-on activities. The plate method, which is used in the Meals Made Easy for Diabetes program, was originally developed in 1970 in Sweden and was adapted by dietitians in the Idaho Diabetes Care and Education practice group to better fit American foods (Rizor and Richards, 2000).

Hood River County implemented Healthy Changes for Living with Diabetes (NCOA, 2004). The original 25 week program was reduced to a 10 week course in order to work within the time frame stipulated by the study; thus, a number of sessions were combined rather than eliminated and the topics covered are bulleted in Table 3.2.

Participants attended the intervention program, which was held in clinics serving a high percentage of Hispanic patients, one time per week for 10 weeks or 2 times per week for ~6 weeks depending on the county. Class size was limited to ~15 participants, which included both the individual with diabetes and their support person(s) (~7-8 participants with diabetes and ~7-8 support participants). Thus, in order to reach an

n size of at least 40 for participants with diabetes each county ran the intervention program 3 times.

Attendance for both the person with diabetes and their social support person(s) were taken at each class (Appendix 11). The number of sessions attended by each participant was tabulated and used as a variable in determining successful participation. To be included in the final analysis participants with diabetes must have attended 6 out of 10 classes. Additionally, the community health worker filled out a weekly evaluation sheet after each class to summarize how the class went and identify which outcome variables were discussed (Appendix 12).

#### Assessments/Evaluation

Prior to, and following the intervention program, assessment data from the participants was gathered in each county. Baseline (pre) and follow up (post) data were obtained with the help of Spanish speaking community health workers according to the schedule outlined in Tables 3.3 and 3.4. The evaluation of the intervention program used pre and post-test questionnaires to determine whether participants' eating behavior (SWAN food frequency questionnaire) and physical activity level (based on the Healthy Changes questionnaire, NCOA, 2004) changed due to participation in the diabetes education program. Change in diabetes risk factors before and after the program were also assessed using anthropometric (height, weight, and waist circumference), clinical (blood pressure), and biochemical measurements (blood glucose, HgbA1c, insulin, and blood lipid profile) which provided additional data to help in the evaluation of the

**Table 3.3 Data collection schedule for participant with diabetes**

	Pre-intervention	Post-intervention
Informed consent document	√	
SWAN food frequency questionnaire (FFQ)	√	√
Enrollment questionnaire (including diagnosed diseases and medication use)	√	
Follow up questionnaire		√
Fasting blood draw*	√	√
Anthropometric/clinical measurements: Height (cm) Weight (kg) Resting blood pressure (mm Hg) Waist circumference (in)	√ √ √ √	√ √ √ √

\*Glucose, insulin, HgbA1c, high density lipoprotein-cholesterol, low density lipoprotein-cholesterol, triglycerides, total cholesterol

**Table 3.4 Data collection schedule for support participant**

	Pre-intervention	Post-intervention
Informed consent document	√	
Enrollment questionnaire	√	
Follow up questionnaire		√

program.

The primary outcome variables were carefully reviewed with the community health workers by the researchers. How these variables were measured are outlined in Table 3.5. The secondary outcome variable and how it was measured is outlined in Table 3.6.

**Table 3.5 Primary outcome variables and assessment method**

Primary Outcome Variables	Assessment Method
1. Increase servings of whole grains, fruits, and vegetables/day 2. Decrease saturated fat intake (gms/day)	1 & 2. SWAN Food Frequency Questionnaire (FFQ)
3. Increase minutes/week of physical activity	3. Hispanic Family Diabetes Project Enrollment and Follow up Questionnaires (for participant with diabetes)
4. Improve insulin resistance (HOMA-IR*) (Yokoyama et al, 2003)	4. HOMA-IR formula using fasting insulin (mU/L) and fasting plasma glucose (mg/dL)
5. Improve fasting plasma glucose (mg/dL), HgbA1c (%), and insulin (mU/L) 6. Improve fasting high density lipoprotein-cholesterol (mg/dL), low density lipoprotein-cholesterol (mg/dL), triglycerides (mg/dL), and total cholesterol (mg/dL)	5 & 6. Biochemical measurements

\*HOMA-IR=FIRI (fasting immunoreactive insulin) mU/L x  $\frac{\text{FPG mg/dL}}{405}$

**Table 3.6 Secondary outcome variable and assessment method**

Secondary Outcome Variable	Assessment Method
1. Support participant will increase supportive behavior directed toward partner with diabetes	1. Hispanic Family Diabetes Project Enrollment and Follow up Questionnaires (for support participant)

Anthropometric, Clinical, and Biochemical Measurements. Height (cm), weight (kg), and blood pressure (mm Hg) were measured using standard equipment that has been established at each of the clinic sites designated in this project. Waist circumference (in) was measured using either a plastic or steel measuring tape (NIH, 2000). Finally, a fasting (~8 hour fast) venous blood sample (~50 ml) was collected pre and post-intervention during this study. A healthy diabetic snack was provided after the blood draw.

Fasting glucose, insulin, HgbA1c, and blood lipids (HDL-cholesterol, LDL-cholesterol, triglycerides, and total cholesterol) were analyzed in HRC by LabCorp (Seattle, WA) and in MC by Quest Diagnostics (Seattle, WA and Portland, OR); and copies of results were placed in the participants medical record. Insulin resistance was calculated using the homeostasis model assessment (HOMA-IR) method equation using fasting plasma glucose (mg/dL) and insulin (mU/L). This indirect measurement of insulin sensitivity is highly correlated with the euglycemic-hyperinsulinemic clamp method (clamp-1R) used for assessing insulin resistance and can be used to assess insulin sensitivity in normal weight and moderately obese individuals with and without type 2 diabetes (Yokoyama et al, 2003).

Diet and Eating Behaviors. One of the most practical methods for measuring food intake is by using a food frequency questionnaire (FFQ) (Murata et al, 2004). FFQs ask respondents to report their frequency of consumption of a list of foods over a specific period of time. They are designed to capture an individual's usual dietary intake. Food frequency analysis is widely regarded as a valid method for evaluation of dietary habits and does not require a detailed interview (Willett, 1994; Hu et al, 1999; Feskanich et al,

1993; Riley and Blizzard, 1995). Dietary behaviors (over the past month) and nutrient intakes for the participant with diabetes were assessed using the Spanish SWAN (Study of Women's Health Across the Nations) Food Frequency Questionnaire (FFQ) from Block Dietary Data Systems, Berkeley, CA. The SWAN questionnaire is a modification of the full-length 1995 Block food frequency questionnaire (Subar et al, 2001; Huang et al, 2000; personal communication with Dr. Wakimoto), with approximately 10 additional questions added for different ethnicities that were identified during focus group testing. The form was first developed in English, then professionally translated (including back translations) into Spanish. This questionnaire was recommended by Block Dietary Data Systems as it includes additional foods that may be important for Hispanics. The SWAN FFQ was scanned and analyzed by Block Dietary Data Systems for energy, nutrients, and food group servings. Data was returned to the investigators where it was analyzed for diet outcome variables.

Physical Activity and Self-care Management Behaviors. Physical activity and self-care management behaviors of the participant with diabetes was initially assessed using the Hispanic Family Diabetes Project Enrollment Questionnaire. Post-intervention, the Hispanic Family Diabetes Project Follow up Questionnaire was used. Both questionnaires were derived from the surveys used in the Healthy Changes program; however, they were developed more specifically for the Hispanic population in mind with the help of culturally sensitive staff members from both counties.

Typical activity levels and minutes/week of physical activity for the last 7 days was assessed using these questionnaires, along with self-care management questions

related to blood glucose monitoring and medication use. This information provided a comprehensive assessment of the effectiveness of the intervention in motivating positive changes in physical activity and self-care management behaviors from baseline.

Pedometers were used as a method of motivating participants to increase physical activity and to help them self-monitor changes in physical activity. Pedometers are cost-effective tools for measuring changes in physical activity under free-living conditions (Welk et al, 2000). Participants were provided with Walk4Life 2505 pedometers in the beginning of the intervention and were given instructions on their use. All participants were encouraged to walk outside of class and record steps taken each day in a journal. Facilitators were to ask participants every week in class how many steps they walked the previous week and this provided a quick means of assessing level of movement that occurred between sessions.

Social Support Participant. Each person with diabetes was to recruit one or more social support persons who attended each class session with them and were to be participating members of the study. If the support participant was  $\leq 18$  years of age they were not included in the study. The support participant filled out a questionnaire prior to the educational intervention and following the last educational class that asked questions regarding his/her relationship with the diabetic partner they were supporting.

At the beginning of the educational program support individuals also received a pedometer and were given instructions on its use. They were encouraged to walk outside of class and keep a journal of steps taken each day. The support individual was encouraged to exercise along with their partner who has diabetes.



## Statistical Analysis

A two-way repeated measures ANOVA using 2 groups (Multnomah and Hood River counties) and 2 time points (pre/post intervention) was used to determine if the intervention program improved outcome measures (i.e., diet and blood variables) or if there were differences between groups (Kirk, 1995). If there were no interactions related to groups, then data was combined to examine the impact of the intervention with all participants over time. Except for frequencies, results are expressed as mean values with standard deviations. Statistical significance was defined as  $p < 0.05$ . The SAS software package (version 9.1) was used for statistical analysis.

## CHAPTER 4 – RESULTS

We tested a culturally appropriate diabetes education intervention program in 2 Oregon counties that focused on nutrition, physical activity, and self-care management for Hispanic participants with diabetes, to determine if lifestyle and medical diabetic risk factors improved upon completion of the program. All participants were assessed before and after the intervention program.

Initially, a total of 64 participants with diabetes signed up for the classes (30 in HRC, and 34 in MC). However, only 63% of participants in HRC met the attendance criteria (at least 60% attendance) vs. 74% in MC; thus, the sample size dropped to 44. Work, illness, and lack of transportation were cited as reasons for this decrease in attendance.

### **PARTICIPANT CHARACTERISTICS**

The study population in both counties were predominantly females, ~46-48 years of age on average, with less than a high school education (Table 4.1). Additionally, participants with diabetes in HRC had been clinically diagnosed with diabetes on average ~ 8 years and in MC ~ 5 years. Both county participants had at least 2 chronic diseases (including diabetes) and > 75% of participants indicated they had someone who supported them in managing their diabetes.

Based on the acculturation questionnaire (see Appendix 10), the participants from HRC were non-native born, spoke primarily Spanish, and had resided in the U.S. > 3 years. In MC, the community health worker was not as familiar with the participants and did not complete the questionnaire; however, she indicated that Spanish was the primary

**Table 4.1 Characteristics of participants with diabetes by county**

	Hood River n=19	Multnomah n=25
Gender (female/male) (n)	16/3	22/3
Age (years)	48 $\pm$ 10.2 <sup>a</sup>	46 $\pm$ 16.3 <sup>a</sup>
Education (grade level)	5 $\pm$ 3.8 <sup>a</sup>	4 $\pm$ 3.9 <sup>a</sup>
Diabetes diagnosis (years)	8 $\pm$ 6 <sup>a, b</sup>	5 $\pm$ 6 <sup>a</sup>
Chronic diseases (#)	2	2
Support person n (%)	15 (79%)	19 (76%)

<sup>a</sup> mean  $\pm$  standard deviation (SD)

<sup>b</sup> 1 missing data

language and that literacy level was low.

Table 4.2 shows additional demographic data obtained pre and post-intervention.

The primary difference between the 2 counties was that > 70% of participants in HRC worked outside of the home, compared to < 20% of MC participants. More than 70% of participants were receiving medication treatment for diabetes, but only 2 participants (11%) in HRC were using insulin compared to 4 participants (16%) in MC post-intervention. Use of other diabetic medication, besides insulin, was higher in HRC (pre/post-intervention) compared to MC.

There were a number of similarities between the 2 counties. The participants were predominately non-smokers, with similar BMIs (~30-31 kg/m<sup>2</sup>), waist circumferences (~39-40" or ~99-102 cm), and levels of health insurance coverage (< 35% overall); and each county had an increase in the number of participants (post-intervention) whose blood pressure fell within the ADA recommended guidelines (2005).

**Table 4.2 Characteristics of participants with diabetes by county – pre vs. post-intervention**

	Hood River n=19		Multnomah n=25	
	Pre	Post	Pre	Post
Work outside home n (%)	14 (74%)	14 (74%)	3 (12%)	4 (16%)
Diabetes medication n (%)	17 (89%)	16 (84%)	18 (72%)	20 (83%) <sup>a</sup>
Oral agents (n)	15	14	15	16
Insulin (n)	0	0	1	1
Oral and insulin (n)	2	2	2	3
Smoke (n)	0	0	1	0
BMI (kg/m <sup>2</sup> )	31 $\pm$ 4.6 <sup>b</sup>	30.8 $\pm$ 4.5 <sup>b</sup>	30.9 $\pm$ 5.8 <sup>b</sup>	30.5 $\pm$ 5.9 <sup>b</sup>
Blood pressure < 130/80 mm Hg (n)	4	10 <sup>c</sup>	8 <sup>a</sup>	11
Waist circumference in (cm)	40.3 (102)	40.1 (102) <sup>c</sup>	40.3 (102) <sup>d</sup>	39.0 (99) <sup>a</sup>
Health insurance n (%)	3 (16%)	5 (26%)	7 (28%)	8 (32%)

<sup>a</sup> 1 missing data<sup>b</sup> mean  $\pm$  SD<sup>c</sup> 3 missing data<sup>d</sup> 2 missing data

## DIETARY OUTCOMES

We hypothesized that participants would increase intake (servings/day) of vegetables, fruit, and whole grains as a result of the intervention. As shown in Table 4.3, mean vegetable intake was significantly different between the sites ( $p < 0.05$ ), but there was no change as a result of the intervention ( $p = 0.41$ ). There was no change in mean

**Table 4.3 Changes in diet outcome measures within each county and between counties**

	Hood River n=14 <sup>a</sup>			Multnomah n=23 <sup>a</sup>		
	Pre (mean $\pm$ SD)	Post (mean $\pm$ SD)	Mean value average over time period *	Pre (mean $\pm$ SD)	Post (mean $\pm$ SD)	Mean value average over time period*
Vegetables (servings/day)	1.32 $\pm$ 1.2	1.21 $\pm$ 0.8	1.26	2.10 $\pm$ 1.2	1.86 $\pm$ 0.9	1.98
Fruit (servings/day)	0.96 $\pm$ 0.5	0.96 $\pm$ 0.3	--	1.57 $\pm$ 1.2	0.86 $\pm$ 0.7*	--
Whole grains (servings/day)	0.51 $\pm$ 0.4	0.79 $\pm$ 0.5*	0.65	0.30 $\pm$ 0.3	0.42 $\pm$ 0.3*	0.36
Saturated fat (grams/day)	16.14 $\pm$ 12	11.43 $\pm$ 8	--	23.87 $\pm$ 10	12.10 $\pm$ 6*	--

<sup>a</sup> Participants whose FFQs were not excluded due to errors (i.e., too many questions skipped or an abnormally high amount of food reportedly eaten).

\* p < 0.05

fruit intake in HRC over time, while mean fruit intake in MC significantly decreased ( $p < 0.05$ ) by nearly a serving/day. Fruit juice was not used as part of the participant's fruit intake. However, on average, participants in HRC did not drink fruit juice and participants in MC consumed 1 serving/day at baseline that decreased to zero post-intervention. When mean fruit/vegetable servings were combined post-intervention ( $2.17 = \text{HRC}$ ;  $2.72 = \text{MC}$ ), both counties fell below the 2005 Dietary Guidelines for Americans level of a minimum of 5 fruits and vegetables/day.

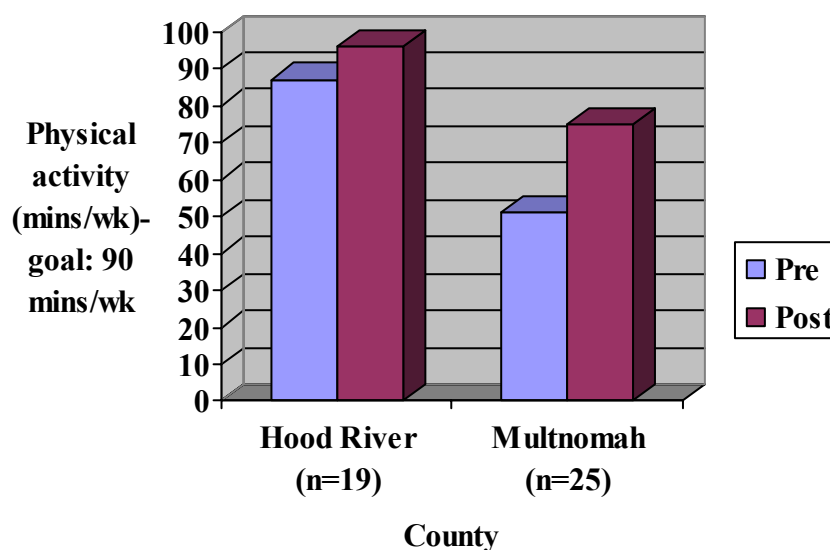
Whole grain data are also given in Table 4.3. For whole grain intake (mean servings/day) there was a significant site and time effect. HRC participants consumed significantly more ( $p < 0.01$ ) whole grains than MC and both counties showed a significant increase ( $p < 0.05$ ) mean whole grain consumption after the intervention. Again, both counties fell below the 2005 Dietary Guidelines for Americans recommendation of at least 3 servings (ounce equivalents) of whole grains/day.

We also hypothesized that participants would self-report eating less saturated fat (grams/day) as a result of the intervention program. As shown in Table 4.3, MC had a higher mean saturated fat intake at baseline compared to HRC ( $\sim 24$  gm/day vs  $16$  gm/day). Mean saturated fat intake decreased in both counties due to the intervention, but this decrease was only significant in MC ( $p < 0.05$ ). Mean saturated fat intake levels for both counties post-intervention ( $\sim 11$  gm/day for HRC and  $\sim 12$  gm/day for MC) were within the Daily Value (DV) recommendation established by the U. S. Food and Drug Administration of  $< 20$  gm saturated fat for a 2,000 calorie diet and  $< 25$  gm saturated fat for a 2,500 calorie diet.

## PHYSICAL ACTIVITY OUTCOMES

We also hypothesized that participants would self-report participating in more minutes of physical activity per week (other than activity performed during work) due to the intervention program. As shown in Figure 4.1, physical activity (mins/wk) increased in both counties due to the intervention; although these increases were not statistically significant ( $p = 0.34$ ).

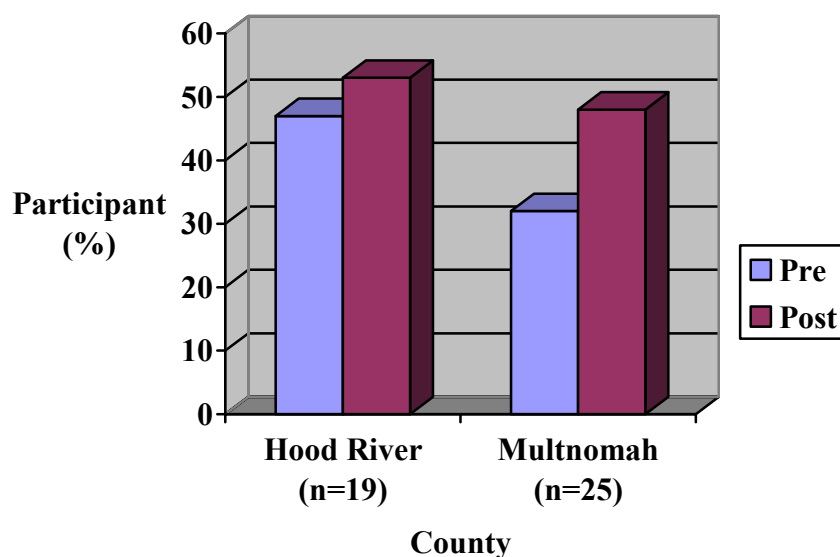
**Figure 4.1 Change in physical activity (mins/wk) by county**



Prior to the educational intervention, participants in HRC averaged 87 minutes of physical activity/week vs. 96 minutes post-intervention, which represents ~10% increase in physical activity. In MC, participants exercised 51 mins/wk pre vs. 75 mins/wk post-intervention (~47% increase). The participants in HRC were more active (mins/wk); however, participants in MC experienced a greater percentage increase in mins/wk of physical activity post-intervention. We also examined the number of

participants that met the ADA guidelines of ~30 minutes physical activity, 3 times/week (Figure 4.2). Approximately 47% of participants in HRC met the ADA guidelines at baseline vs. 53% post-intervention. In MC, the percentage of those meeting the recommendation at baseline was 32% vs. 48% post-intervention.

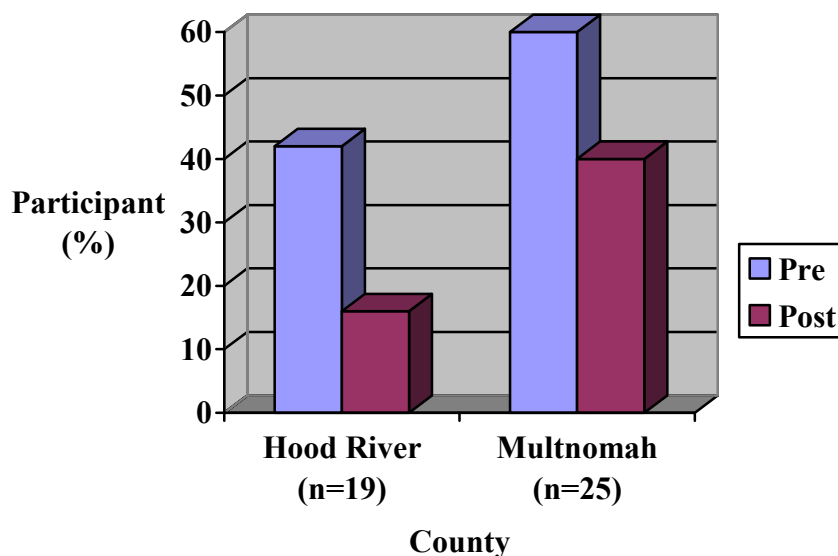
**Figure 4.2 Participants who exercised  $\geq 3$  days/wk, ~30 mins/day by county**



We also examined the number of participants that did no physical activity (0-1 day/week) at baseline to determine if the intervention motivated them to begin exercising (Figure 4.3). Prior to the intervention, 42% of the participants in HRC and 60% in MC reported only 0-1 day/week of physical activity, while after the intervention, these numbers dropped to 16% and 40%, respectively. Although 74% of HRC participants worked outside of the home (vs. 16% of participants in MC post-intervention), they were more physically active than participants in MC. The type of



**Figure 4.3 Participants who exercised 0-1 day/wk, ~30 mins/day by county**



work that participants in HRC did outside of the home post-intervention included: manual labor (n=7), desk job (n=2), service industry (n=3), and other (child care, sewing, cleaning) (n=2). The primary physical activity for participants in both counties was walking and most participants (> 70%) did not use fitness facilities. Money and not enough time were cited as factors that made it difficult to join.

## **BIOCHEMICAL OUTCOMES**

Approximately 70-90% of participants used some type of medication (insulin or oral hypoglycemics) to manage their diabetes. Fifty-two percent of participants, in both counties combined, were on glucophage, a glucose lowering medication. In order to determine changes due to the intervention we eliminated from the analysis those participants on insulin, those who changed their oral hypoglycemic/antihyperlipidemic medications during the intervention, and anyone who did not follow the blood draw

protocol. Thus, 23 participants were in the analysis of the biochemical data.

### HOMA-IR

Mean HOMA-IR values, a measure of insulin resistance, are shown in Table 4.4. There were no changes in HOMA-IR ( $p = 0.56$ ) due to the intervention; however, values were improving for MC (-0.62). Currently there are no standard normal ranges for HOMA-IR; however, it is generally agreed that values  $\geq 3$  is considered insulin resistant (Nasution et al, 2006; Osei et al, 2005). For example, in a study completed by Inukai and colleagues (2005), a HOMA-IR value of  $\geq 3$  was considered high in individuals with type 2 diabetes. Applying this value to our data, the average HOMA-IR value was high for participants in MC, who had HOMA-IR values that were ~60% higher than HRC ( $p = 0.053$ ). Level of physical activity may be one factor contributing to the lower HOMA-IR values for participants in HRC, who were more active (mins/wk) compared to MC (see Figure 4.1). Physical activity is known to improve insulin resistance (O'Donovan et al, 2005).

### Blood glucose/Insulin/HgbA1c

We also examined whether the intervention would improve fasting plasma glucose (FPG), insulin, and HgbA1c, these data are presented in Table 4.4. There were no significant changes due to the intervention for mean FPG and HgbA1c; however, sites were significantly different for mean insulin ( $p < 0.05$ ). The mean fasting insulin levels in both counties were within the normal range established by Quest Diagnostics of  $< 17\text{mU/L}$ ; however, the mean fasting insulin for participants in MC was ~ twice the

**Table 4.4 Changes in biochemical outcome measures within each county and between counties**

	Hood River n=9 (mean age = 50 + 9) <sup>a</sup>			Multnomah n=14 (mean age = 44 + 17) <sup>a</sup>		
	Pre (mean ± SD)	Post (mean ± SD)	Mean value average over time period*	Pre (mean ± SD)	Post (mean ± SD)	Mean value average over time period*
HOMA-IR <sup>b</sup>	2.72 ± 1.77	3.00 ± 2.21	--	5.61 ± 3.41	4.99 ± 3.16	--
Fasting plasma glucose (mg/dL)	134 ± 59	142 ± 76	--	137 ± 54	125 ± 42	--
Fasting insulin (mU/L)	8.1 ± 3.7	8.3 ± 4.9	8.2	16.9 ± 9.1	16.7 ± 10.9	16.8
HgbA1c <sup>c</sup> (%)	8.0 ± 1.8	7.9 ± 1.9	--	6.9 ± 1.6	7.0 ± 1.4	--
Total cholesterol (mg/dL)	178 ± 34	178 ± 34	--	170 ± 27	165 ± 29	--
Low density lipoprotein- cholesterol (LDL) (mg/dL)	101 ± 30	99 ± 26	--	89 ± 20	93 ± 23 <sup>d</sup>	--
High density lipoprotein- cholesterol (HDL) (mg/dL)	47 ± 8	48 ± 6	47	42 ± 6	41 ± 5	42
Triglycerides (mg/dL)	145 ± 36	155 ± 68	--	192 ± 72	161 ± 91	--

<sup>a</sup> Participants on no insulin, no oral hypoglycemic/antihyperlipidemic medication changes, all fasting, all values pre/post

<sup>b</sup> Homeostasis model assessment-insulin resistance

<sup>c</sup> Glycosylated hemoglobin

<sup>d</sup> 1 missing data

\* p < 0.05; no time or site by time interaction; only site was significantly different.

level seen in participants in HRC. In addition, 43% of participants in MC had fasting insulin levels  $\geq 17$  mU/L vs. 11% in HRC post-intervention. These elevated insulin levels for participants in MC is one factor in their higher HOMA-IR values.

The mean FPG for both counties was above the goal established by the ADA (2006) of  $< 100$  mg/dL, and 78% of participants in HRC had FPG levels  $\geq 100$  mg/dL vs. 79% in MC post-intervention. However, in MC there was a positive nonsignificant decrease (-12 mg/dL) in average FPG after the intervention, while there were no significant changes in HRC participants.

According to the ADA (2005), the HgbA1c recommendation is  $< 7\%$ . However, more stringent glycemic goals, HgbA1c as close to normal ( $< 6\%$ ) as possible without significant hypoglycemia, may further reduce complications (ADA revisions, 2006). Neither county met the ADA recommendation of  $< 7\%$  for mean HgbA1c post-intervention; however, 33% of participants in HRC met this goal vs. 71% in MC. Overall, post-intervention, participants in MC had lower mean FPG and HgbA1c levels compared to those in HRC, although the values were not significantly different.

### Blood Lipids

We also measured changes in TC, LDL-cholesterol, HDL-cholesterol, and TG plasma levels to determine the impact of the intervention on these blood lipid parameters. These data are presented in Table 4.4. There were no significant changes due to the intervention for TC, LDL-cholesterol, and TG; however, counties were significantly different ( $p < 0.05$ ) for mean HDL-cholesterol averaged over time. Mean values for TC, LDL-cholesterol, and HDL-cholesterol were typically within normal ranges, with only

17% of participants using lipid lowering medication in both counties combined.

However, 52% were on glucophage, a glucose lowering medication, which can decrease TC, LDL-cholesterol, and TG, and increase HDL-cholesterol (Pronsky, 2004).

The higher HDL-cholesterol level in HRC participants coincided with their higher level of physical activity (mins/wk). Despite the fact that the participants in MC had lower HDL-cholesterol levels, the average HDL-cholesterol value in both counties did not fall  $< 40$  mg/dL (ATP III, 2001). Of participants in HRC, only 11% had HDL-cholesterol levels  $< 40$  mg/dL, compared to 36% in MC post-intervention.

Mean TC concentration did not change due to the intervention and mean values in both counties (pre/post) met the recommendation of  $< 200$  mg/dL (ATP III, 2001). In HRC, 67% of participants had a cholesterol level  $< 200$  mg/dL vs. 86% in MC post-intervention. There were no significant changes in mean LDL-cholesterol due to the intervention for either county; however, mean values met the recommendation of  $< 100$  mg/dL (ATP III, 2001). Of participants in HRC, 56% had LDL-cholesterol values that met the recommendation vs. 62% in MC.

Table 4.4 also shows the changes in average TG. Mean TG level did not change significantly due to the intervention and mean values in both counties post-intervention were considered high ( $\geq 150$  mg/dL) according to the ADA (2005). Of participants in HRC, 56% had TG levels that were high ( $\geq 150$  mg/dL) compared to 50% in MC.

## **SUPPORT PARTICIPANTS**

We also examined the role of support in helping the participant with diabetes improve their diabetes risk factors and follow the intervention guidelines. We did not

have enough support participants that met our criteria for attendance ( $\geq 60\%$  of classes); thus, the n size was low. The characteristics of the support participants are outlined in Table 4.5.

**Table 4.5 Characteristics of support participants who attended  $\geq 60\%$  of classes by county**

	Hood River n=1	Multnomah n=8
Gender (female/male) (n)	1/-	7/1
Age (years)	25	$40 \pm 15.1^a$
Education (grade level)	9	$6 \pm 3.7^a$
Relationship (family/friend)	1/-	6/2
Time known (years)	25	$22 \pm 19.5^a$

<sup>a</sup> mean  $\pm$  SD

The change in number of supportive activities conducted by the support partner increased in both counties. The supportive behavior in HRC went from 5 to 6 supportive activities post-intervention and the supportive behavior in MC went from 3 to 4.

Examples of supportive behavior include the following: helping with diabetes meal planning, medication reminders, and exercising with partner. In addition, participants with diabetes were asked if their support partner helped them manage their disease, post-intervention. In HRC, 89% indicated the support was helpful and in MC, 96%.

## **CHANGES IN SELF-EFFICACY**

One of the major components of the Social Cognitive Theory is self-efficacy, (Bandura, 1986), which describes the confidence an individual has for performing a behavior in challenging or tempting situations. Assuming adequate incentive(s) and

skill(s), self-efficacy is one of the most important characteristics that determine behavioral change (CDC, 2002).

In this study, we assessed self-efficacy level associated with making changes in diet and physical activity. These results are in Table 4.6. Self-efficacy level increased in each county post-intervention for all 3 questions; however, participants in MC showed a higher percentage point change compared to participants in HRC with regard to all 3 questions.

**Table 4.6 Changes in self-efficacy level regarding diet and physical activity by county**

	Hood River n=19		Multnomah n=25	
	Pre	Post	Pre	Post
How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?	58%	63%	44%	72%
How confident do you feel that you can choose appropriate foods to eat when you are hungry?	37%	63%	52%	80%
How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?	74%	83% <sup>a</sup>	60%	80%

<sup>a</sup> 1 missing data

## PROGRAM EVALUATION

Table 4.7 outlines the percentage of participants who were satisfied with specific

**Table 4.7 Participants with diabetes who were satisfied with various aspects of the diabetes education program by county**

	Hood River n=19	Multnomah n=25
Overall program	100%	100%
Program leaders	100%	100%
Guest presenters	95%	100%
Handouts/written materials	94% <sup>a</sup>	96%
Contact/support received	100% <sup>a</sup>	100%
Convenient time	100%	100%
Convenient location	100%	96%
Accessible room	100%	100%
Comfortable room	100%	100%
Recommend program to others	100%	100%

<sup>a</sup> 1 missing data

areas of the education program. Ten areas were evaluated and in all areas there was a score of 90% or above. Thus, participants with diabetes in both counties were overwhelming satisfied with the diabetes educational program.

### **PROGRAM INFLUENCE ON MANAGING DIABETES**

Participants in both counties were also asked if the educational program helped them to manage various aspects of their diabetes. According to Table 4.8, the areas with  $\geq 95\%$  of success for both counties were: 1) achieve personal goals with diet, 2) achieve



**Table 4.8 Participants who felt the diabetes education program helped them to manage various aspects of their diabetes by county**

	Hood River n=19	Multnomah n=25
Achieve personal goals with diet	100%	100%
Achieve personal goals with exercise	95%	96%
Communicate better with health care provider	84%	100% <sup>a</sup>
Use community resources	83% <sup>a</sup>	79% <sup>a</sup>
Manage diabetes (i.e., blood sugar, medication, and diet)	100%	96%

<sup>a</sup> 1 missing data

personal goals with exercise, and 3) manage diabetes. Scores were not as high for communicate better with health care provider in HRC, and use of community resources (i.e., exercise programs, MedicAlert, and materials written in Spanish offered by the National Diabetes Education Program) for both counties.

### **PARTICIPANT INPUT REGARDING PROGRAM**

Overall, the participants liked a number of things about the educational programs (see Tables 4.9 and 4.10). Some commonalities between the counties with regard to what they liked best include the following: 1) how to eat healthy and exercise, 2) group environment, 3) instructors, and 4) support. In addition, Tables 4.9 and 4.10 outline items that participants liked least about the program and suggestions for improvement. A

**Table 4.9 Participant (individual with diabetes and support) input regarding the educational program in Hood River County**

What they liked best (n=18)	What they liked least (n=1)
<ul style="list-style-type: none"> <li>• Everything</li> <li>• Support</li> <li>• Dinamicas (ice breakers)</li> <li>• How to eat healthy, exercise</li> <li>• Learning about others in group</li> <li>• Communication with instructors and their interest</li> <li>• Guest speakers (i.e., yoga instructor)</li> <li>• Group environment</li> <li>• Dialysis information</li> <li>• Explanation of diabetes</li> <li>• How to take care of oneself</li> </ul>	<ul style="list-style-type: none"> <li>• When participants arrive late</li> </ul>
Suggestions for program improvement (n=10)	
<ul style="list-style-type: none"> <li>• More exercise during class</li> <li>• Ways to exercise at home</li> <li>• Invite more people</li> <li>• Follow up for consistency</li> <li>• Games</li> <li>• Many activities</li> <li>• Continue the classes</li> <li>• Tour a dialysis unit</li> </ul>	

number of suggestions are well worth considering for future educational programs; i.e., more exercise and cooking during class, more games and activities, follow up for consistency, and ongoing support groups.

**Table 4.10 Participant (individual with diabetes and support) input regarding the educational program in Multnomah County**

What they liked best (n=25)	What they liked least (n=7)
<ul style="list-style-type: none"> <li>• Healthy food preparation/recipes</li> <li>• Portion control</li> <li>• How to choose healthy food</li> <li>• Opportunity to cook</li> <li>• Easy to understand, including plate method</li> <li>• Interaction with group and leader</li> <li>• The participants and instructors</li> <li>• To learn about exercise</li> <li>• Pedometers</li> <li>• Information received</li> <li>• Support</li> <li>• Meeting together and advice</li> <li>• How treated</li> <li>• Books/CDs about relaxing</li> <li>• How to have control</li> <li>• How to prevent diabetes</li> <li>• Conversation motivated them to increase self-esteem</li> </ul>	<ul style="list-style-type: none"> <li>• Needed more time to learn more</li> <li>• Needed to receive this program when diagnosed</li> <li>• Had to travel by bus and pick up daughter after</li> <li>• Had trouble attending all classes</li> <li>• Needed more participants</li> <li>• Course ended too soon</li> <li>• Distance to travel</li> </ul>
Suggestions for program improvement (n=14)	
<ul style="list-style-type: none"> <li>• To run classes like this more often</li> <li>• Repeat important classes; ie, grocery store visit</li> <li>• A prevention program</li> <li>• Cooking more</li> <li>• Ongoing support groups</li> <li>• Change snacks</li> <li>• Flyers about programs for Latinos with diabetes</li> <li>• Raise consciousness within Hispanic community re: prevention and good health</li> </ul>	

## CHAPTER 5 – DISCUSSION

This research project was a pilot study to test a culturally appropriate diabetes education intervention program for Hispanic individuals with diabetes to determine if diabetic risk factors would improve. The most significant findings of this study were that the intervention significantly increased ( $p < 0.05$ ) intakes of whole grains in both counties, while saturated fat intake significantly decreased ( $p < 0.05$ ) in MC participants only. There were also significant differences between the counties for diet and blood parameters. Participants in MC ate significantly more ( $p < 0.05$ ) vegetables compared to participants in HRC, while fruit intake significantly decreased ( $p < 0.05$ ). In addition, participants in HRC ate significantly more ( $p < 0.05$ ) whole grains, compared to those in MC. Average fasting insulin level for participants in MC was significantly higher ( $p < 0.05$ ) compared to participants in HRC; and participants in HRC had significantly higher ( $p < 0.05$ ) mean HDL-cholesterol values.

This study was unique in that it examined the effectiveness of a diabetes education program offered to Hispanic individuals with diabetes in both rural and urban settings, within a manageable time frame, and included outcome variables related to change in dietary and exercise habits, blood lipids and insulin resistance. To date, Hispanic individuals with diabetes have received only limited attention in the research literature. Only 3 primary intervention studies have examined the effectiveness of an education program on improving lifestyle behaviors and biomarkers for the treatment of diabetes in the Hispanic population (Elshaw et al, 1994; Brown and Hanis, 1999; Banister et al, 2004) (see Table 1.1). The intervention program examined by Brown and Hanis (1999) more closely resembles this study; however, the intervention last 1 year and

attendance was only 50% post-intervention, contact with participants was limited to 2 times/month, and the outcome variables did not include diet, exercise, and change in blood lipids or insulin resistance.

## **PARTICIPANT CHARACTERISTICS**

The study population in both counties were similar with regard to age, gender, education level, smoking status, primary language, BMI, and waist circumference. The main demographic difference between the 2 counties was participants in HRC were ~ 4 times more likely to work outside of the home. However, participants in MC predominately work in the service industry during the summer when tourism is at its peak, and classes were not offered at this time.

## **DIETARY OUTCOMES**

One focus of the intervention program was to educate the participants about improving dietary habits. There was a positive change in whole grain consumption and saturated fat intake in both counties as a result of the intervention. Although participants in both counties had a significant increase ( $p < 0.05$ ) in mean whole grain consumption overtime, participants in HRC ate significantly more ( $p < 0.05$ ) whole grains compared to those in MC. Despite positive changes in whole grain consumption, participants in both counties ate less than 1 serving/day, which is below the recommendation of 3/day.

Mean saturated fat intake decreased in both counties after the intervention; however, this decrease was only significantly different ( $p < 0.05$ ) in participants in MC who consumed ~ 70% more saturated fat compared to participants in HRC at baseline.

After the intervention, both counties met the Daily Value recommendation of < 20 grams saturated fat for a 2,000 calorie diet and < 25 grams saturated fat for 2,500 calories. This desirable intake of saturated fat in both counties coincides with the normal mean plasma levels for TC and LDL-cholesterol that were observed post-intervention.

Mean fruit and vegetable intake did not improve in either county post-intervention and in MC fruit intake actually decreased significantly ( $p < 0.05$ ). One possible reason for this decrease in fruit intake is that fruit contains a high amount of carbohydrate, which tends to be controlled in a diabetic diet; in addition, cost may have played a role.

Average vegetable intake was significantly higher in participants in MC vs. HRC, but there were no significant changes with the intervention. It is unclear as to why vegetable intake did not change; however, both cost and carbohydrate content may have been a factor. According to a study conducted by Jetter and Cassady (2006), low income consumers may be unable to afford the cost of eating more healthful foods to meet dietary recommendations. Post-intervention intake of fruits and vegetables in both county participants fell below the recommendation of a minimum of 5 fruits and vegetables/day (2.17 = HRC; 2.72 = MC).

In summary, positive changes were seen in whole grain and saturated fat intake as a result of the intervention program. Our results are consistent with dietary intake in the general population suggesting that a majority of Americans are consuming an inadequate quantity of fruits and vegetables (Nelson et al, 2002). More emphasis needs to be placed in both education programs regarding low cost fruit and vegetable options that are available year round.

## PHYSICAL ACTIVITY OUTCOME

Although physical activity (minutes/week) did not significantly increase due to the intervention, both counties showed a trend toward increased physical activity (minutes/week) post-intervention. The participants in HRC were more active (minutes/week) than those in MC; however, participants in MC experienced a greater percentage increase in minutes/week of physical activity post-intervention (47% vs. 10% for HRC). Pedometers were provided as an incentive to increase physical activity above baseline measures. In addition, facilitators asked participants every week in class how many steps they walked the previous week and effort was praised.

We also compared how many participants met the ADA guidelines of ~30 minutes physical activity, 3 times/week. Approximately 47% of participants in HRC met these guidelines at baseline, which increased to 53% post-intervention. In MC, 32% of participants met the recommendations at baseline, which increased to 48% post-intervention. In addition, the number of participants that did no physical activity (0-1 day/week) at baseline compared to after the intervention was examined. Both counties saw a positive trend in this area. Forty-two percent of participants in HRC were not active at baseline, which decreased to 16% post-intervention. In MC, 60% were not active at baseline, while only 40% reported 0-1 day/week PA post-intervention. These data differ to what was reported by Nelson and colleagues (2002), where 31% of individuals with type 2 diabetes reported no physical activity.

In summary, participants in HRC were more physically active (minutes/week) compared to participants in MC; however, participants in MC experienced a greater percentage increase in minutes/week of physical activity post-intervention (47% vs. 10%

for HRC). The higher self-reported physical activity of participants in HRC may have contributed to their significantly higher ( $p < 0.05$ ) mean HDL-cholesterol and significantly lower ( $p < 0.05$ ) mean insulin levels compared to those in MC. Participants in both counties were given pedometers and were held accountable for how many steps they took every week, both of which may have contributed to the positive trend seen in physical activity.

## **BIOCHEMICAL OUTCOMES**

Although there were no significant changes in blood assessment variables after the intervention, there were modest beneficial changes in some outcome variables: HgbA1c, LDL-cholesterol, and HDL-cholesterol improved in HRC; while HOMA-IR, FPG, insulin, TC, and TG improved in MC. The intervention lasted 6-10 weeks, which may not have been long enough to see significant changes in blood variables using a community intervention setting. The sites differed significantly ( $p < 0.05$ ) at baseline for mean HDL-cholesterol, which was higher in participants in HRC and for mean insulin level, which was lower. However, values in both counties were within recommended levels. Furthermore, the mean HOMA-IR value was lower for participants in HRC compared to MC, although the differences were not significant ( $p = 0.053$ ). The HOMA-IR value for participants in MC improved after the intervention, while HRC showed no change. Participants in MC were more insulin resistant based on their mean HOMA-IR and insulin values, while their HDL-cholesterol was lower. All 3 of these values coincide with the lower level of physical activity that was exhibited in MC. The higher mean insulin value in participants in MC is an indication that the insulin is available, but due to



the elevation in FPG it is not effective in moving glucose into the cells. In an effort to lower FPG, the pancreas is producing more insulin; however, as body fat increases, insulin receptors diminish in number or in function. Consequently, the cells respond less sensitively to insulin and become more insulin resistant.

There were no significant differences between sites over time for FPG, HgbA1c, TC, LDL-cholesterol, and TG. The mean FPG for both counties was above the goal established by the ADA (2006) of < 100 mg/dL, and neither county met the ADA recommendation of < 7% for mean HgbA1c post-intervention. Twenty-two percent of participants in HRC had FPG levels within the goal established by the ADA, compared to 21% in MC. In addition, 33% of participants in HRC had HgbA1c levels with the ADA recommendation, compared to 71% in MC. Participants in MC had lower mean FPG and HgbA1c levels post-intervention compared to those in HRC, and they also had a higher number of participants on no oral hypoglycemic medication (36% vs. 22% in HRC).

Although this study did not specifically examine how often participants self-monitored FPG, there was a positive trend in this behavior in both counties. The percentage of participants who did not monitor their FPG prior to the intervention was 47% (HRC) and 28% (MC), this improved somewhat to 26% and 25% respectively, after the intervention.

Participants in both counties had near normal to normal average values for TC and LDL-cholesterol, despite only 17% of participants (both counties combined) on lipid lowering medications. However, 52% were taking glucophage, which can decrease TC

and LDL-cholesterol (Pronsky, 2004). Overall, participants in MC had lower mean TC and LDL-cholesterol levels compared to those in HRC post-intervention, although the differences were not significant.

Mean TG levels were elevated for both counties and did not change for participants in HRC and showed no significant improvement for participants in MC (-31 mg/dL). Only 44% of participants in HRC had TG levels < 150 mg/dL post-intervention vs. 50% in MC. Elevated TG level is an independent risk factor for CHD (ATP III, 2001). Factors that contribute to elevated TG in the general population include obesity, physical inactivity, and different diseases; i.e., type 2 diabetes and chronic renal failure (ATP III, 2001). When TG level is borderline high (150-199 mg/dL), emphasis should be placed on weight reduction and increased physical activity.

Participants in both counties had mean TG levels  $\geq$  150 mg/dL, a mean waist circumference > 35" (88.9 cm) (for women), and mean FPG levels  $\geq$  110 mg/dL. All 3 of these are risk factors for metabolic syndrome (see Table 2.2), which represent a constellation of lipid and non-lipid risk factors of metabolic origin that are closely linked to a generalized metabolic disorder called insulin resistance (ATP III, 2001). The risk factors of metabolic syndrome in aggregate enhance risk for CHD at any given LDL-cholesterol level (ATP III, 2001). Excess body fat (particularly abdominal obesity) and physical inactivity promote the development of insulin resistance, but some individuals are genetically predisposed to it (ATP III, 2001).

In summary, although there were no significant changes in blood assessment variables after the intervention, there were modest changes in some outcome variables. Blood values that are linked to physical activity were better in participants in HRC who

were more physically active. As a group, participants in MC had better control of their diabetes; however, they were more insulin resistant compared to those in HRC.

Lipid profiles for both counties, except for TG, were within recommended guidelines, and participants in both counties had borderline high levels of mean TG levels, which is an independent risk factor for CHD.

### **SUPPORT PARTICIPANTS**

We did not have enough support participants that met our criteria for attendance ( $\geq 60\%$  of classes); thus, the n size was low (1 = HRC; 8 = MC). Support individuals could not commit to regular attendance due to work or changes in the weather. Despite the fact that designated support participants could not always attend the classes, other supportive individuals were able to attend in some instances. This was particularly the case in HRC, where every class had a room full of support participants, including children.

Of the support participants that met the attendance criteria, the change in number of supportive activities conducted by the support partner increased in both counties post-intervention (5 to 6 supportive activities in HRC vs. 3 to 4 in MC). In addition,  $\geq 89\%$  of participants with diabetes in both counties indicated their support partner helped them manage their disease, post-intervention.

### **PARTICIPANT FEEDBACK**

Based on participant feedback, participation in the program was successful due to several factors. First, self-efficacy level increased in both counties for 3 questions related

to diet and physical activity. Second, 100% of participants in both counties were satisfied with the educational program. Last,  $\geq 95\%$  of participants in both counties felt the education program helped them to achieve personal goals with diet and exercise, and manage their diabetes.

Overall, the participants liked a number of things about the education program including: 1) how to eat healthy and exercise, 2) group environment, 3) instructors, and 4) support. In addition, suggestions for program improvement included more exercise and cooking during class, more games and activities, follow up for consistency, and ongoing support groups.

## **LIMITATIONS**

This intervention pilot study has a number of limitations. Several of these limitations were either in the design of the study or out of the researchers control, and deserve to be mentioned as follows:

- The study recruited a small number of volunteers ( $n = 44$ ) with self-reported diabetes rather than randomly selecting participants from a large sample.
- The small sample size limits the generalization of the findings.
- Participants were used as their own controls and the study did not include a non-treatment control group.
- The study reached a small percentage of the Hispanic male population, either because of work conflicts or disinterest in the topic.

Classes were limited to 10-15 participants each, which included both the individual with diabetes and their support partner. In order to increase the sample size, the classes were run 3 times in each county. Therefore, each county had 3 separate cohorts that were combined within each county to meet the current  $n$  size. However,

each county utilized the same facilitators for all 3 classes, which helped to promote consistency in program administration.

An additional limitation was some data were self-reported. This could bias the results from a measurement perspective as some individuals tend to underreport what they eat and over report how much they exercise. Also, self-reported post-test results may get worse rather than improve since the educational program may increase the participant knowledge and they may be better equipped to answer the question correctly. Underreporting is always an issue with diet assessments. Although there appeared to be some underreporting in this study, there were no weight changes of physiological significance.

This study was further limited with the use of 2 different educational programs. The counties were contracted through DHS to implement the intervention programs. The state allowed each county to select the program that would work best in their community; thus, the researchers had no control over which educational program was selected. We attempted to address this problem by identifying outcome variables that were common to each program and to educate the community health workers regarding the primary educational objectives of the study as well as the outcome variables. Additionally, the community health workers filled out a weekly evaluation sheet after each class to summarize how the class went and identified which outcome variables were discussed. Since fruit/vegetable intake did not increase as anticipated, it is recommended that community health workers demonstrate their knowledge of the subject matter to those with higher education in the topic to be discussed, prior to facilitating an education

program.

Another limitation in this study was each county used different laboratory companies to analyze the blood work. To evaluate whether the companies were consistent in their analyses, fasting blood samples were taken from the same researcher, on the same day in each county, about 1 hour apart. Cholesterol, HDL-cholesterol, LDL-cholesterol, and FPG values were similar between Quest in MC and LabCorp in HRC; however, values from Quest were 10% higher for TG, 17% higher for insulin, and 9% lower for HgbA1c. The difference in insulin values may have been attributed to stress.

An additional limitation was counties were not consistent following the time frame outlined in the study. A 10 week intervention was to be offered with a week prior to and after the intervention, used for assessment gathering. In total, this would have been 12 weeks. Some classes followed this schedule; however, some had to be shortened due to conflicts with participant work schedules and to avoid offering classes over the holidays at the end of the year.

The SWAN FFQ also presented limitations. Although this validated questionnaire was in Spanish, it did not differentiate between what kind of bread was eaten. Both refined grain and whole grain bread were combined into one category of bread on the FFQ. Thus, any changes in whole grain bread intake were not analyzed, which may have had an impact on the whole grain outcome. In addition, the questionnaire was too lengthy and detailed to administer. The participants were predominately low literacy and therefore the facilitators had to read the FFQs to many of the participants. Thus, the assessment gathering process took more time than originally anticipated. Participants grew tired answering the questions, which may have effected

the accuracy of their answers. A validated FFQ that is simple, short, low in literacy, and community friendly is needed to assess if food habits are changing. Furthermore, the assessment gathering forms were intimidating to some participants, particularly the IRB informed consent document.

Another limitation was non-researchers collected the data because the researchers did not know Spanish. Blood work protocol was not always followed and there was missing data, both of which contributed to the decrease in n size. In addition, those collecting the data were not familiar with the questionnaires which increased the time needed for the assessment gathering process.

## **STRENGTHS**

This study includes a number of strengths. Strategies taken from previous intervention studies already cited were incorporated into this pilot study to help ensure successful outcomes:

- Use of bilingual, bicultural low literacy materials.
- Interventions provided in Spanish.
- Bilingual, culturally sensitive community health workers, with current knowledge of diabetes as facilitators.
- An educational component that raised awareness on how physical activity and nutrition can improve complications that may be associated with type 2 diabetes.
- Involvement of at least one support person to increase awareness and support for behavioral changes in the individual with diabetes.
- The opportunity for participants to meet weekly, in a group setting, for education, social support, and community building.

An additional strength was most participants were read the assessment questionnaires to help alleviate any problems with literacy skills. To help strengthen the self-reported results for diet and physical activity, blood biochemical and anthropometric measurements were taken.

Furthermore, the education classes were taught at the same site every week using the same facilitators and the participatory lecture format was used which involves the participants in the learning process. This format is a non-traditional method of teaching as opposed to the traditional method of lecturing. Classes were informal, and facilitators actively involved the participants in either cooking, games, or activities which made learning fun. The curriculum was centered on promoting problem solving skills and peer support. Giving participants the opportunity to share their successes and frustrations and to learn in a cooperative environment was important. Due to the overwhelming participant satisfaction of the education program, this teaching style was well received.

An important strength of this study was the community health workers. They were key to program success in both counties, one factor that emphasizes this success is the improvement in self-efficacy level seen in both counties for 3 questions related to diet and physical activity. The community health workers were able to create a comfortable environment which led to a feeling of trust between themselves and the participants. To encourage attendance, community health workers made reminder phone calls, access was given to bus tickets, incentives were provided, i.e., small gifts, and child care was either provided or children were encouraged to attend. Although incentives may have helped to keep participants engaged in the program, they could have been a confounding factor in this study. The most expensive incentive in this study was the pedometers. Effort could



be made in community health programs to get incentives donated, if budget constraints do not allow for their purchase. A final strength of this study is the participants will have an opportunity to attend a follow up session to hear the findings of the study.

## CHAPTER 6 – CONCLUSION

The purpose of this intervention pilot study was to test whether a culturally appropriate diabetes education program for Hispanic individuals with diabetes and their support person(s), significantly improved both lifestyle and medical diabetic risk factors for diet, physical activity, and biochemical measurements. The following research questions were tested and the results are summarized as follows:

### Primary Research Questions

1. Do participants self-report eating more servings/day of whole grains, fruits, and vegetables after (post) the intervention program than before (pre)?

Hypothesis: Participants will self-report consuming more servings/day of whole grains, fruits, and vegetables after the intervention program than before.

Result: Whole grain intake significantly ( $p > 0.05$ ) improved in both counties; however, there were no significant increases in fruit or vegetable intake.

Thus, the 1<sup>st</sup> hypothesis was accepted for whole grain intake and rejected for fruit and vegetable intake.

2. Do participants self-report eating less saturated fat (gms/day) after the intervention program than before?

Hypothesis: Participants will self-report consuming less saturated fat (gms/day) after the intervention program than before.

Result: Participants in both counties decreased their saturated fat intake after the intervention; however, the change was significant ( $p > 0.05$ ) in MC only. Therefore, the 2<sup>nd</sup> hypothesis was accepted for MC and rejected for HRC.

3. Do participants self-report participating in more minutes of physical activity per week after the intervention program than before?

Hypothesis: Participants will self-report participating in more minutes of physical activity per week after the intervention program than before.

Result: Physical activity (minutes/week) increased in both counties post-intervention; however, the change was not significant. Therefore, the 3<sup>rd</sup> hypothesis was rejected for physical activity.

4. Does insulin resistance in participants improve after the intervention program compared to before the intervention program?

Hypothesis: Insulin resistance in participants will improve after the intervention program compared to before the intervention program.

Result: Despite the positive improvement in mean HOMA-IR value for participants in MC post-intervention, the change was not significant; thus, the 4<sup>th</sup> hypothesis was rejected for HOMA-IR.

5. Do participants improve their diabetes risk factors (fasting glucose, insulin, and HgbA1c) after the intervention program compared to before the intervention program?

Hypothesis: Participants will improve their diabetes risk factors (fasting glucose, insulin, and HgbA1c) after the intervention program compared to before the intervention program.

Result: Although there were some positive trends in glycemic control for both counties, the results were not significant; therefore, the 5<sup>th</sup> hypothesis was rejected for diabetes risk factors.

6. Do participants improve their risk factors for high density lipoprotein-cholesterol (HDL-cholesterol), low density lipoprotein-cholesterol (LDL-cholesterol), triglycerides (TG), and total cholesterol (TC) after the intervention program compared to before the intervention program?

Hypothesis: Participants will improve their risk factors for HDL-cholesterol, LDL-cholesterol, TG, and TC after the intervention program compared to before the intervention program.

Result: Although there were some positive improvements in blood lipids for both counties, the changes were not significant; thus, the 6<sup>th</sup> hypothesis for lipid biomarkers was rejected.

#### Secondary Research Question

1. Do support participants self-report an increase in supportive behavior directed toward their partner with diabetes after the intervention program than before?

Hypothesis: Support participants will self-report an increase in supportive behavior directed toward their partner with diabetes after the intervention program.

Result: We did not have enough support participants that met the criteria for attendance ( $\geq 60\%$  of classes); thus, the n size was too small to analyze.

To summarize, the intervention significantly increased ( $p < 0.05$ ) mean intakes of whole grains in both counties, while average saturated fat intake significantly decreased ( $p < 0.05$ ) in MC. In addition, mean fruit intake significantly decreased ( $p < 0.05$ ) after the intervention for participants in MC, and the sites were significantly different ( $p <$

0.05) with regard to mean vegetable and whole grain intake. There were significant differences ( $p < 0.05$ ) between the counties for mean insulin and HDL-levels; however, no significant changes occurred in blood assessment variables post-intervention.

Furthermore, participants in both counties reported more minutes/week of physical activity after the intervention. Participants in MC experienced a greater percentage increase in physical activity post-intervention, compared to those in HRC, 47% increase vs. 10%, respectively.

Diabetes intervention studies with Hispanic individuals have received only limited attention. This study was unique in that the intervention was completed in both urban and rural settings, in a manageable time frame, with outcome variables that included change in dietary and exercise habits, blood lipids, and insulin resistance. The intervention resulted in modest changes in some outcome variables but a longer intervention with more emphasis on good nutrition and exercise is necessary to significantly improve lifestyle behaviors and biomarkers for the treatment of diabetes.

This study was a collaborative process between the state of Oregon, 2 counties in Oregon, and OSU. It expanded on, as well as greatly added to, what has already been investigated in the research literature in the area of culturally appropriate diabetes education programs for the Hispanic population. This pilot study examined what did, and did not work, not only in the assessment of behavior and biomarker changes, but also in educating the Hispanic community about diabetes prevention and treatment. Based on participant feedback, the education program was successful because a culturally appropriate intervention was used. Thus, this pilot intervention has the potential of being refined and developed into a county and/or statewide program.

## IMPLICATIONS

This study helped to address the tremendous need for culturally appropriate diabetes education programs geared toward the Hispanic population whom bear a disproportionate burden of type 2 diabetes, and with whom traditional interventions have been ineffective. Although this study only reached a small percentage of the eligible population, participants that were involved were grateful to have had the opportunity to learn about diabetes prevention and treatment in a comfortable group environment where they could share their frustrations and successes. Culturally appropriate approaches that included language, food, cultural beliefs, the importance of family, and a cooperative learning environment, facilitated by bilingual/bicultural community health workers, that did not rely on lectures and reading materials; were successfully incorporated into the education program and were enthusiastically received by the participants. The programs would not have been as successful without the use of community health workers who were critical to the success of the program. They were trusted and respected in the community, and offered a welcoming, as well as non-threatening environment, in which to learn.

Not only did this pilot study address a great educational need, it examined what was and was not successful, in educating and assessing behavior change in the Hispanic community. This information can be used by counties to help secure funding for similar interventions in this underserved population. In addition, since the cooperative learning/participatory lecture teaching style was so well received, counties should consider using existing resources to provide care in a different way; i.e., from the individual case management model (1 on 1 education) to group classes that incorporate

this non-traditional method of teaching. More of the eligible population would be reached in a classroom setting.

One of the most significant findings from this pilot study was how enthusiastically the non-traditional method of teaching was received. The learning needs and styles of the audience must be taken into consideration during curriculum development and facilitation. The Hispanic participants, in both counties, were overwhelmingly satisfied with the overall program that actively involved them in the learning process. The following quote summarizes this positive learning event:

“I hear, I forget;  
I see, I remember;  
I do, I understand;  
I practice, I master;  
I master, I enjoy.”  
(Author unknown)

In addition, the opportunity to learn in a cohort environment provided valuable support within the group. This supportive group setting may have been more beneficial to some, compared to the support offered at home, where changes in diet and physical activity may not have been as welcomed.

Despite the welcoming environment and culturally appropriate approaches, significant improvements were only seen in mean whole grain consumption in both counties, and mean saturated fat intake in MC. Simply educating participants about lifestyle changes to help manage diabetes was not enough to produce significant changes in fruit and vegetable intake, physical activity, and blood values in the short term. It appears that the program was making some positive changes in physical activity level and blood values; however, the 6-10 week program was not long enough to see significant

changes in the community setting.

Offering a longer intervention of 12-16 weeks may provide enough time to see significant changes in biochemical measurements in the community setting. A longer intervention would also give more time to incorporate weight loss strategies, and allow extra time for exercising and cooking in class, which were 2 suggestions participants listed for program improvement. Although weight loss was not a component of this intervention, it should be incorporated into the curriculum of future interventions since the mean BMI of participants in this study was  $\sim 30\text{-}31 \text{ kg/m}^2$  and even a modest weight loss of  $\sim 10\%$  would be of benefit.

## **RECOMMENDATIONS FOR FUTURE RESEARCH**

A culturally appropriate diabetes education program, similar to what was tested in this study, needs to be investigated in a randomized trial in a larger segment of the Hispanic population in both rural and urban settings. A randomized trial is often considered the “gold standard” of the prospective study design. In the case of randomized trials, participants are randomly assigned to treatment or control groups; thus, allowing comparison between groups as to any differences in the outcome of interest as a result of the treatment.

In this study, the participants in both counties were different with regard to eating habits, physical activity level, and biochemical measurements. It appears that environment (rural vs. urban) may have been a factor in these differences; and if so, interventions should be designed based on what area the participants live in. Participants in MC (urban setting) tended to eat more saturated fat, vegetables and fruits, and less



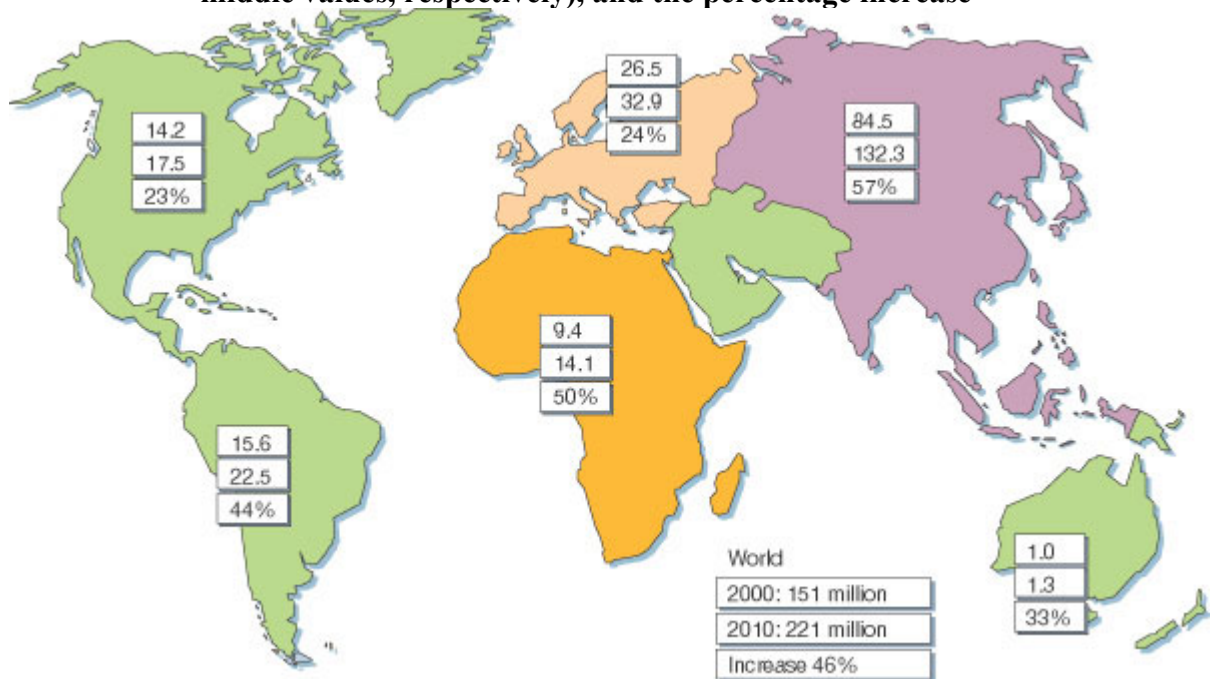
whole grains compared to those in HRC (rural setting). In addition, they were less physically active, and their blood values confirmed this. However, participants in this urban setting were in better glycemic control and may have received more aggressive medical treatment.

An additional recommendation is that shorter, low literacy questionnaires that measure lifestyle behavior changes, need to be developed for the Hispanic population and tested for reliability and validity. Furthermore, in order to examine behavior changes and whether they continue after the intervention has ended, additional studies need to investigate participant behavior and biomarker changes at follow up points in time; i.e., 6 months and 1 year.

Finally, changes in human behavior and lifestyle over the last century have resulted in a dramatic increase in the incidence of diabetes worldwide (Zimmet et al, 2001). Diabetes is now taking its place as one of the main threats to human health in the 21<sup>st</sup> century (Zimmet et al, 2001). As we look to the future, the global projections for diabetes are grim. Figure 6.1 represents these projections from 2000 to 2010. There is a 23% projected increase of type 2 diabetes in the U.S., and worldwide it is expected to be 46%.

After taking so long to gain recognition, interest in diabetes is now mounting rapidly and it is an exciting time for researchers and clinicians involved in the study and treatment of the disease. The problem has crept up on an unsuspecting public health community. Diabetes is likely to remain a huge threat to public health in the years to come (Zimmet et al, 2001). In the absence of effective and affordable interventions for

**Figure 6.1 Numbers of people with diabetes (in millions) for 2000 and 2010 (top and middle values, respectively), and the percentage increase**



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diabetes, the frequency will escalate, with the main impact being seen in underserved minorities. Thus, research is needed on how to make education programs sustainable in a community, and available to those in need, in an effort to benefit the welfare of our society.

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## APPENDICES

## Appendix 1

### Spanish SWAN (Study of Women's Health Across the Nations) Food Frequency Questionnaire

<input type="checkbox"/> Hispano	<input type="checkbox"/> Blanco, no hispano
<input type="checkbox"/> Hispanic	<input type="checkbox"/> White, not Hispanic
<input type="checkbox"/> Africanoamericano	<input type="checkbox"/> Chino
<input type="checkbox"/> African American	<input type="checkbox"/> Chinese
<input type="checkbox"/> Japonés	<input type="checkbox"/> Otro
<input type="checkbox"/> Japanese	<input type="checkbox"/> Other

¿Aproximadamente, cuántas veces ha seguido una dieta para perder peso?  
About how many times have you gone on a diet to lose weight?

☐ Nunca ☒ 1-2 ☐ 3-5 ☐ 6-8 ☐ 9-11 ☐ 12 o más  
Never 1 or more times 2 or more times 3 or more times 4 or more times 5 or more times 6 or more times

POR FAVOR, NO ESCRIBA EN ESTA ÁREA / PLEASE DO NOT WRITE IN THIS AREA

PORTA FOR, NO ESQUINA EN ESTA AREA? PLEASE DO NOT WRITE

**SERIAL #**

¿Qué tipo de grasas o aceite usa usualmente para freír, sofreír, cocer o sazonar sus alimentos?

(Sólo marque una o dos de los que siguen)

What kinds of fat or oil do you usually use to fry or stir-fry, or to simmer or season your food?

(Mark only one or two.)

☐ No lo sé o sin aceite ☐ Mantequilla ☐ Aceite de maíz o vegetal ☐ Manteca, tocino, manteca de tocino  
Don't know or no oil Butter Corn oil, vegetable oil Lard, fatback, bacon fat

☐ Margarina ☐ Aceite de oliva o de canola ☐ Margarina baja en grasas ☐ "Crisco"  
Margarine Olive oil or canola oil Low-fat margarine Crisco

¿Cuando toma jugo de naranja, con qué frecuencia escoge una marca que esté fortificada con calcio?

When you drink orange juice, how often do you drink a calcium-fortified brand?

☐ Usualmente ☐ A Veces ☐ Rara vez ☐ No se  
Usually Sometimes Rarely Don't know

Quando consume estos alimentos, ¿con qué frecuencia come una versión de los mismos baja en grasa o sin grasa?

When you eat the following foods, how often do you eat a low-fat or non-fat version of that food?

Queso ☐ Siempre bajo en grasa ☐ A veces ☐ Rara vez bajo en grasa ☐ N/A  
Cheese Always low-fat Sometimes Rarely low-fat

Helado o yogurt ☐ Siempre bajo en grasa ☐ A veces ☐ Rara vez bajo en grasa ☐ N/A  
Ice cream or yogurt Always low-fat Sometimes Rarely low-fat

Aderezo de ensalada ☐ Siempre bajo en grasa ☐ A veces ☐ Rara vez bajo en grasa ☐ N/A  
Salad dressing Always low-fat Sometimes Rarely low-fat

Pastel o galletitas ☐ Siempre bajo en grasa ☐ A veces ☐ Rara vez bajo en grasa ☐ N/A  
Cake or cookies Always low-fat Sometimes Rarely low-fat

¿Con qué frecuencia le añade sal a los alimentos en la mesa? ☐ Rara vez ☐ A veces ☐ A menudo  
How often do you add salt to your food at the table? Seldom Sometimes Often

¿Con qué frecuencia come la piel del pollo? ☐ Rara vez ☐ A veces ☐ A menudo ☐ N/A  
How often do you eat the skin on chicken? Seldom Sometimes Often

¿Con qué frecuencia come la grasa de la carne? ☐ Rara vez ☐ A veces ☐ A menudo ☐ N/A  
How often do you eat the fat on meat? Seldom Sometimes Often

¿Cómo le gusta la carne? ☐ Poco cocinada ☐ Mediana ☐ Bien cocinada ☐ N/A  
How do you like your meat cooked? Rare Medium Well done



Durante el pasado año, ¿ha tomado con regularidad vitaminas o minerales (al menos una vez por semana)?  
During the past year have you taken any vitamins or minerals regularly (at least once a week)?

☐ No, no regularmente      ☐ Sí, con bastante regularidad  
No, not regularly      Yes, fairly regularly

EN ESTE CASO, ¿QUÉ ES LO QUE TOMA CON REGULARIDAD?  
(IF YES) WHAT DO YOU TAKE FAIRLY REGULARLY?

[illegible]

Si toma vitamina C o vitamina E:  
If you take Vitamin C or Vitamin E:

¿Cuántos miligramos de vitamina C toma normalmente, los días que la toma?  
How many milligrams of vitamin C do you usually take, on the days you take it?

☐ 100   ☐ 250   ☐ 500   ☐ 750   ☐ 1000   ☐ 1500   ☐ 2000   ☐ 3000+   ☐ No lo sé / Don't know

¿Cuántas IU de vitamina E toma normalmente, los días que la toma?

How many IUs of vitamin E do you usually take, on the days you take it?

☐ 100    ☐ 200    ☐ 300    ☐ 400    ☐ 600    ☐ 800    ☐ 1000    ☐ 2000+    ☐ No lo sé / Don't know

POR FAVOR, NO ESCRIBA EN ESTA ÁREA / PLEASE DO NOT WRITE IN THIS AREA

[illegible]

**SERIAL #**

La sección que sigue trata de sus hábitos de nutrición normales aproximadamente el pasado año. Esto incluye todas sus comidas y bocadillos, en la casa, en restaurantes o comidas para llevar.

The next section is about your usual eating habits over the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out.

Por favor díganos con qué frecuencia come cada alimento. Por ejemplo, dos veces a la semana, tres veces al mes, etc.

Please tell us how often, on average, you eat each food. For example, twice a week, three times a month, and so forth.

Además por favor díganos cuánto come de cada alimento por usual. A veces preguntamos en "que cantidad", por ejemplo cuántos pedazos, tales como 1 huevo, 2 huevos, o 3 huevos. Por favor, díganos cuánto de estos alimentos come en los días que los come.

Also, please tell us how much you usually eat of each food. Sometimes we ask "how much" as number of pieces, such as 1 egg, 2 eggs or 3 eggs. Please tell us how many you eat, on the days you eat them.

A veces preguntamos "que cantidad" como A, B, C o D. VEA LAS FOTOS INCLUIDAS. Si usted no tiene estas fotos: A=1/4 taza, B=1/2 taza, C=1 taza, D=2 tazas.

Sometimes we ask "how much" as A, B, C or D. LOOK AT THE ENCLOSED PICTURES. If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D=2 cups.

TIPO DE ALIMENTO TYPE OF FOOD	QUÉ FRECUENCIA HOW OFTEN								CUÁNTO CADA VEZ HOW MUCH EACH TIME					
	UNA O MENOS VECES AL MES LESS THAN ONCE PER MONTH	1 AL MES PER MONTH	2 AL MES PER MONTH	1 VEZ PER WEEK	2 VEZES PER WEEK	3 VEZES PER WEEK	4 VEZES PER WEEK	5 O MÁS VEZES PER WEEK	TODOS LOS DÍAS EVERY DAY	Vea las fotos de porciones A-B-C-D See portion pictures for A-B-C-D				
Guineos/plátanos/bananas Bananas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Manzanas o puré de manzanas Apples, applesauce	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Ciruela, ciruela pasa, jugo de ciruela Prunes, or prune juice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Melocotones/duraznos, albaricoques, enlatados o secos Peaches, apricots, canned or dried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Melocotones/duraznos, albaricoques, frescos, en estación Peaches, apricots, fresh, in season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Chinas/naranjas o toronjas en estación, no incluyendo jugo Oranges or grapefruit, in season, not including juice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Cantalupo, melón de color anaranjado, en estación Cantaloupe, in season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> 1/8	<input type="checkbox"/> 1/4	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1
Mango o papaya, en estación Mangoes or papayas, fresh, in season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Sandia, fresca, en estación Watermelon, in season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Fresas, frambuesas, etc., en estación Strawberries, other berries, in season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D



TIPO DE ALIMENTO TYPE OF FOOD	CON QUÉ FRECUENCIA HOW OFTEN								CUÁNTO CADA VEZ HOW MUCH EACH TIME					
	NUNCA O MENOS DE UNA VEZ AL MES	1 AL MES	2-3 AL MES	1 A LA SE- MANA	2 A LA SE- MANA	3-4 A LA SE- MANA	5-6 A LA SE- MANA	7 O MÁS A LA SE- MANA	TODOS LOS DÍAS	Vea las fotos de porciones A-B-C-D See portion pictures for A-B-C-D				
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON.	2-3 PER MON.	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	EVERY DAY						
¿Cuántas veces come los siguientes vegetales/verduras, incluyendo frescas, congeladas, enlatadas o en comida china? How often do you eat the following vegetables, including fresh, frozen, canned or in stir-fry?														
Habichuelas verdes, ejotes String beans, green beans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Petit puas/chicharos/guisantes Peas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Habichuelas/frijoles, todos estilos, o en burritos, refritos, etc. Beans like pinto or kidney beans, refried beans, or in bean burritos or 'chili with beans'	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Maíz/elote Corn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Reñoños o germinaciones de alfalfa, "sprouts" Alfalfa sprouts, including on sandwiches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Reñoños como en comida china Regular bean sprouts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Tomates, jugo de tomate Tomatoes, tomato juice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Salsa, salsa de tomate Salsa, ketchup, taco sauce	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas cucharadas	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Brócoli/brecol Broccoli	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Coliflor o coles de Bruselas, coleritas de Bruselas Cauliflower or brussels sprouts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Espinaca, crudas o cocidas Spinach, cooked or raw	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Hojas de mostaza, de berza, nabo, acelga, etc. Mustard greens, turnip greens, collards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Repollo/col, ensalada de repollo/col picada Cole slaw, cabbage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuánto	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Zanahorias o guisantes con zanahorias Carrots, or mixed vegetables containing carrots	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Ensalada verde Green salad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Aderezo o aliño para ensalada, o mayonesa, regular o baja en grasa ("Lowfat") Salad dressing & mayonnaise, regular or lowfat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas cucharadas	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Papas fritas French fries and fried potatoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	¿Cuántas	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D

TIPO DE ALIMENTO TYPE OF FOOD	CON QUÉ FRECUENCIA HOW OFTEN								CUÁNTO CADA VEZ HOW MUCH EACH TIME				
	NUNCA O MENOS DE UNA VEZ AL MES NEVER OR LESS THAN ONCE PER MONTH	1 AL MES	2-3 AL MES	1 A LA SE- MANA	2 A LA SE- MANA	3-4 A LA SE- MANA	5-6 A LA SE- MANA	7 O MÁS DÍAS	Vea las fotos de porciones A-B-C-D See portion pictures for A-B-C-D				
		1 PER MON.	2-3 PER MON.	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	EVERY DAY					
Otras papas sin freír, incluyendo hervidas, al horno, majadas o en ensalada de papa White potatoes not fried, incl. boiled, baked, mashed & in potato salad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Batatas, camotes Sweet potatoes, yams	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
*Tofu/requesón de soya Tofu, bean curd	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sustitutos de carne hechos con soya, como soy burgers Meat substitutes made from soy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
¿Alguna vez come carne, pollo, pavo o pescado? Si <input type="checkbox"/> No (si no, pase al * más abajo) Do you ever eat chicken, meat or fish? Yes <input type="checkbox"/> No (if no, skip to * below)													
Hamburguesas, burritos de res, tacos de res, picadillo, en casa o de restaurante Hamburgers, cheeseburgers, beef burritos, beef tacos, at home or in a restaurant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuánta Carne	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bistec o rosbif (carne de res, costillas, los platos mixtos están más abajo.) Beef roasts, steaks, sandwiches (Mixed dishes are a separate item.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hígado, incluyendo hígado de pollo Liver, including chicken livers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuánto	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cerdo/marrano, incluyendo chuletas, asado o camitas Pork, including chops, roasts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuánto	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pollo frito, en casa o de restaurante Fried chicken, at home or in a restaurant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cantidad de piezas medianas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pollo o pavo/guajolote, asado o a la parrilla, incluyendo sandwiches/tortas Chicken or turkey, roasted or broiled, including on sandwiches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pollo en caldo, en platos mixtos o en burritos Chicken stew, chicken casserole or in burritos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pescado frito o sandwich/torta de pescado, en casa o de restaurante Fried fish or fish sandwich, at home or in a restaurant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Atún, ensalada de atún, platos mixtos con atún Tuna, tuna salad, tuna casserole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuánto del atún	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mariscos como camarones/gambas, langosta, cangrejo, ostras, etc. Shellfish such as shrimp, crab, oysters, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Otros pescados, a la parrilla, al horno Other fish, broiled or baked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
* Caldo de res, platos mixtos con res o de verduras Beef or vegetable stew or pot pie	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>





TIPO DE ALIMENTO TYPE OF FOOD	CON QUÉ FRECUENCIA HOW OFTEN										CUÁNTO CADA VEZ HOW MUCH EACH TIME				
	NUNCA O MENOS DE UNA VEZ AL MES NEVER OR LESS THAN ONCE PER MONTH	1 AL MES	2-3 AL MES	1 A LA SE- MANA	2 A LA SE- MANA	3-4 A LA SE- MANA	5-6 A LA SE- MANA	7-10 A LA SE- MANA	TOODOS LOS DÍAS	2+ AL DÍA	Vea las fotos de porciones A-B-C-D See portion pictures for A-B-C-D				
		1 PER MON.	2-3 PER MON.	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	7-10 PER WEEK	EVERY DAY	2+ PER DAY					
Panecillos, bizcochitos, "muffins", como de "bran", incluyendo de McDonalds, etc. Biscuits, muffins, including fast food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
"Bagels", "English muffins", pan de hamburguesa Bagels, English muffins, hamburger buns	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cada vez	<input type="checkbox"/> 1/2	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Pan, incluyendo pan blanco, pan francés, de trigo integral, etc. Asegúrese de incluir "sandwiches" o tortas. Bread, including white bread, French, whole wheat, etc. Remember to include sandwiches.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos rebanadas cada vez	<input type="checkbox"/> rebanada slice	<input type="checkbox"/> rebanadas slices	<input type="checkbox"/> rebanadas slices	<input type="checkbox"/> rebanadas slices
Pan de maíz, panecillos de maíz Corn bread, corn muffins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos pedazos	<input type="checkbox"/> unidad piece	<input type="checkbox"/> unidades pieces	<input type="checkbox"/> unidades pieces	<input type="checkbox"/> unidades pieces
Meriendas, entrecomidas o bocadillos como nachos, papas con queso, etc. Snacks like nachos with cheese, potato skins with topping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Bocadillos salados como papitas fritas, palomitas de maíz, chicharrón de puerco, galletas saladas, plátanos fritos. Salty snacks, like potato chips, corn chips, popcorn, crackers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Manti/cacahuete, mantequilla de maní/orema de cacahuete. Peanuts, peanut butter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cucharadas	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Margarina en pan, papas, vegetales/verduras, etc. Margarine on bread or on potato/vegetables, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cucharitas	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
Mantequilla en pan, papas/vegetales/verduras Butter on bread or on potato/vegetables, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos cucharitas	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
<b>GOLOSINAS/DULCES SWEETS</b>															
Helado/hielo/mantecado, regular o bajo en grasas Ice cream, regular or lowfat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Donas, pastel, pan dulce Doughnuts, pastry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Galletitas, bizcocho, pastel, regular o bajos en grasa, "lowfat" Cookies or cake, regular or lowfat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Pastel de calabaza/calabazón, batata/camote, flan de calabaza, cazuela Pumpkin pie, sweet potato pie	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Otros pasteles de fruta Other pies, fruit dumpings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D
Dulce de chocolate, barras de chocolate Chocolate candy, candy bars	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cuántos	<input type="checkbox"/> A	<input type="checkbox"/> B	<input type="checkbox"/> C	<input type="checkbox"/> D





TIPO DE ALIMENTO TYPE OF FOOD	CON QUÉ FRECUENCIA HOW OFTEN								CUÁNTO CADA VEZ HOW MUCH EACH TIME				
	NUNCA O MENOS DE UNA VEZ AL MES	1 AL MES	2-3 AL MES	1 A LA SE- MANA	2 A LA SE- MANA	3-4 A LA SE- MANA	5-6 A LA SE- MANA	7 O MÁS A LA SE- MANA	CUÁNTAS VECES CADA VEZ	1	2	3-4	5+
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON.	2-3 PER MON.	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	7 O MÁS PER WEEK					
Café (no descafeinado) Coffee (not de-caf)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Té verde Green tea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Té negro, té inglés, té chino Black tea, English tea, Chinese tea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crema, "half & half", crema artificial en café o té Cream, half and half or nondairy creamer in coffee or tea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leche en café o té Milk in coffee or tea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Azúcar o miel en café o té o en cereal Sugar or honey in coffee or tea or on cereal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Alimentos que muchos Latinos comen a menudo</b> <b>Additional Foods For Hispanics</b>													
	NUNCA O MENOS DE UNA VEZ AL MES	1 AL MES	2-3 AL MES	1 A LA SE- MANA	2 A LA SE- MANA	3-4 A LA SE- MANA	5-6 A LA SE- MANA	7 O MÁS A LA SE- MANA	CUÁNTAS VECES CADA VEZ	1	2	3-4	5+
Leche evaporada, leche condensada Evaporated or condensed milk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pudín, budín, flan Pudding, Flan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pimientos, chile rellenos or chile dulce verdes cocidos Cooked green peppers, chile rellenos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aguacate, guacamole Avocado, guacamole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chile, ají picante Chili peppers, hot chili sauce	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Salsas tales como sofrito, mole Sauces such as mole, sofrito	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Viandas como plátano macho, plátano, yautía, yuca, ñame Viandas, plantain, cassava	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tortillas de maíz Corn tortillas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tortillas de harina Flour tortillas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Appendix 2

Hispanic Family Diabetes Project Enrollment Questionnaire- for participant with diabetes  
(English and Spanish)

# Hispanic Family Diabetes Project

## Enrollment Questionnaire (Participant with diabetes)



This questionnaire is part of a project to learn how diet and physical activity can affect diabetes management. These questions should be easy for you to answer, and you shouldn't spend too much time on each one. **There are no right or wrong answers.**

Your answers are very important for this project. Please try not to skip questions unless the questionnaire tells you to do so. However, you are free to skip any questions that you would prefer not to answer.

If you have questions about any of the items, please feel free to ask project staff for help.

Office Use Only

Participant ID #:

DATE

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

Site:

## I. Participant Information

Please answer the following questions based on your present situation.

1. What is your present living arrangement?
 

1 Live with spouse or partner	4 Live with spouse/partner and children
2 Live with other relatives	5 Live with unrelated roommates
3 Live with children only	6 Live alone
  
2. Where do you currently live?
  - 1 In my own home
  - 2 In an apartment or other rental
  - 3 In a relative's home
  - 4 Other \_\_\_\_\_
  
3. What is your current marital status?
 

1 Married	4 Divorced
2 Widowed	5 Never married or single
3 Separated	
  
4. Are you male or female?
 

1 Male	2 Female
--------	----------
  
5. Which of the following describes your work status?
  - 1 Work, full-time
  - 2 Work, part-time \_\_\_\_\_ (hours/week)
  - 3 Not working
  - 4 Retired (not working)
  - 5 Homemaker
  
6. If you work outside the home, what type of work do you do?
  - 1 Manual labor (construction, farm work), other \_\_\_\_\_
  - 2 Desk job/office worker
  - 3 Service industry (clerk, food service), other \_\_\_\_\_
  - 4 Other \_\_\_\_\_

7. What is your age? \_\_\_\_\_
8. Were you able to attend school? If yes, how many years of school did you complete?

**Grade** 1    2    3    4    5    6    7    8    9    10    11    12

**College**    1    2    3    4    5

**Graduate School**    1    2    3    4    5+

9. How many years ago were you diagnosed as having diabetes?  
years \_\_\_\_\_ months \_\_\_\_\_

10. When was your last eye exam?

1    less than a year ago  
2    between 1-2 years ago  
3    more than 2 years ago  
4    Other \_\_\_\_\_  
5    Never

11. When was your last dental exam?

1    less than a year ago  
2    between 1-2 years ago  
3    more than 2 years ago  
4    Other \_\_\_\_\_  
5    Never

12. What type of diabetes medication are you taking now?

1    None	4    Insulin and pills, tablets, or capsules that you swallow
2    Pills, tablets, or capsules that you swallow	5    Insulin pump
3    Insulin	

13. Do you smoke?    Yes    No;    if Yes, how many cigarettes in one week? \_\_\_\_\_

14. **Interviewer to fill in** - present height: \_\_\_\_\_ feet \_\_\_\_\_ inches

15. **Interviewer to fill in** - present weight: \_\_\_\_\_ lbs.

16. **Interviewer to fill in** - blood pressure: \_\_\_\_\_

17. **Interviewer to fill in** - waist circumference: \_\_\_\_\_ inches

## II. Physical Health

Please answer the following questions based on your present situation.

1. Would you say your health in general is:

- |                |           |
|----------------|-----------|
| 1    Excellent | 4    Fair |
| 2    Very Good | 5    Poor |
| 3    Good      |           |

2. Has a doctor ever told you that you have any of the following?

	<u>No</u>	<u>Yes</u>
a.    Arthritis	0	1
b.    Asthma, bronchitis If yes, when?_____	0	1
c.    High blood pressure (hypertension)	0	1
d.    Ulcers If yes, when?_____	0	1
e.    Vision problems (besides wearing glasses) If yes, when?_____	0	1
f.    Kidney disease	0	1
g.    Cancer or leukemia	0	1
h.    Thyroid or other glandular disorders	0	1
i.    Chronic back problems	0	1
j.    Amputations due to diabetes complications	0	1
k.    Heart condition (e.g., chest pains, abnormal heart beats, heart attack)	0	1

	<u>No</u>	<u>Yes</u>
l. High cholesterol	0	1
m. High triglycerides	0	1
n. Other ( <i>Name illness(es)</i> _____)	0	1
3. Do you have a health care provider ?	0	1

### III. Self Care/Physical Activity/Diet

The following questions ask about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

How much **total** time (for **entire** week) did you spend on each of the following?

- |  |   |
|--|---|
| 1. Stretching or strengthening exercises (range of motion, using weights, etc.)? | 0 None<br>1 Less than 30 minutes per week<br>2 30 to 60 minutes per week<br>3 1 to 3 hours per week<br>4 More than 3 hours per week |
| 2. Walk/hike for exercise?   | 0 None<br>1 Less than 30 minutes per week<br>2 30 to 60 minutes per week<br>3 1 to 3 hours per week<br>4 More than 3 hours per week |
| 3. Swimming or aquatic exercise?   | 0 None<br>1 Less than 30 minutes per week<br>2 30 to 60 minutes per week<br>3 1 to 3 hours per week<br>4 More than 3 hours per week |

4. Bicycling (including stationary exercise bikes)?	0	None
	1	Less than 30 minutes per week
	2	30 to 60 minutes per week
	3	1 to 3 hours per week
	4	More than 3 hours per week

5. Other aerobic exercise equipment (Stairmaster, rowing, skiing machine, etc.)?	0	None
	1	Less than 30 minutes per week
	2	30 to 60 minutes per week
	3	1 to 3 hours per week
	4	More than 3 hours per week

6. Other aerobic exercise? Please list _____ _____	0	None
	1	Less than 30 minutes per week
	2	30 to 60 minutes per week
	3	1 to 3 hours per week
	4	More than 3 hours per week

How many days during the past week did you:

**Number of Days**

7. Participate in at least 30 minutes total of physical activity? (other than activity performed during your work?)	0	1	2	3	4	5
	6	7				

8. Check your feet for sores?	0	1	2	3	4	5
	6	7				

9. Monitor your blood glucose?	0	1	2	3	4	5
	6	7				

10. Do you have a diabetes meal plan?            Yes    No

If yes, how many days have you followed it in the last week?	0	1	2	3	4	5
	6	7				



11. Are you taking medication for diabetes?    Yes    No

If yes:

What medication are you taking? \_\_\_\_\_

What is the dosage? \_\_\_\_\_

How frequently do you take it?    1 less than 1 time per day  
2 1 time per day  
3 2 times per day  
4 more than 2 times per day

12. Have you been unable to take your medication in the last 3 months?    Yes    No

If yes, how many days were you unable to take your medication?    1 2 days  
2 1 week  
3 4 weeks  
4 Other \_\_\_\_\_

Why were you unable to take your medication? \_\_\_\_\_

#### IV. Supportive Resources

The following questions ask about a variety of different resources that people may use to manage their illness. For each item, check the box that best indicates your experiences over the past year.

**Over the past year:**                      No    Yes

1. Has your doctor explained the results of tests you had done (e.g., cholesterol, blood pressure, A1c)?                      0            1

2. Did you understand the results?                      0            1

3. Have you had health insurance that covered most of the costs of your medical needs including medicine?                      0                      1

4. Have you attended free or low-cost meetings that supported you in managing your diabetes?

0                      1

If yes, what did you attend? \_\_\_\_\_

5. Have you utilized fitness facilities (e.g., YMCA, Curves, 24 hr fitness, local health/sports clubs)?

0                      1

If yes, where did you go? \_\_\_\_\_

If no, why not? \_\_\_\_\_

6. Do you currently have a social support person (e.g., family member or friend) that helps you manage your diabetes?

0                      1

If yes, what is the relationship? \_\_\_\_\_

Family member

Friend

### V. Self-Confidence for Diabetes

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

**NOT                      SOMEWHAT**  
**CONFIDENT      CONFIDENT      CONFIDENT**

1. How confident do you feel that you can follow your diabetes meal plan?



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



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



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



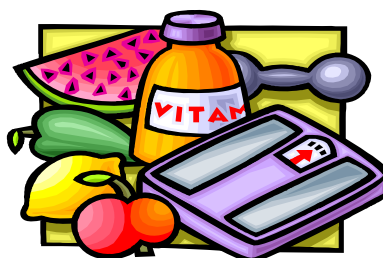
5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?



**You have completed this survey. Thank you!**

# Proyecto Investigación de Diabetes en la Familia Hispana

Cuestionario de inscripción  
(*Participante con diabetes*)



Este cuestionario es parte de un proyecto para aprender cómo la dieta y la actividad física pueden afectar el control de la diabetes. Estas preguntas son muy fáciles de contestar y usted no debería tomar mucho tiempo para contestar cada una. **No hay respuestas correctas ni incorrectas.**

Sus respuestas son muy importantes para este proyecto. Por favor trate de no saltarse preguntas a menos que se lo indique el cuestionario. Sin embargo, siéntase en libertad de no contestar algunas preguntas si usted prefiere no hacerlo.

Si tiene preguntas acerca de algo, por favor siéntase en libertad de pedir ayuda al personal del proyecto.

Office Use Only  
Participant ID #:

DATE

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

Site:

## I. Información del participante

Por favor conteste las siguientes preguntas con base en su situación actual.

1. ¿Cuál es su arreglo actual de vivienda?

- |                                     |   |
|-------------------------------------|---|
| 1 Vive con esposo(a) o compañero(a) | 4 Vive con esposo(a)/compañero(a) y con los hijos         |
| 2 Vive con otros parientes          | <input type="checkbox"/> 5 Vive con personas no parientes |
| 3 Vive con los hijos solamente      | <input type="checkbox"/> 6 Vive solo(a)                   |

2. ¿Dónde vive normalmente?

- 1 En casa propia
- 2 En un apartamento/otro lugar que alquila
- 3 En casa de un pariente
- 4 Otro \_\_\_\_\_

3. ¿Cuál es su estado civil actual?

- |               |                                    |
|---------------|------------------------------------|
| 1 Casado(a)   | 4 Divorciado(a)                    |
| 2 Viudo(a)    | 5 Soltero(a). (Nunca se ha casado) |
| 3 Separado(a) |                                    |

4. ¿Es usted hombre o mujer?

- |          |         |
|----------|---------|
| 1 Hombre | 2 Mujer |
|----------|---------|

5. ¿Cuál de las siguientes situaciones describe su estado de trabajo?

- 1 Trabaja, tiempo completo
- 2 Trabaja, tiempo parcial \_\_\_\_\_(horas por semana)
- 3 No trabaja
- 4 Retirado(a) (no trabaja)
- 5 Ama de casa

6. Si trabaja fuera de casa, ¿Qué tipo de trabajo realiza?

- 1 Trabajo físico (construcción, en el campo), otro\_\_\_\_\_
- 2 Trabajo de escritorio/empleado de oficina
- 3 Industria de servicio (dependiente, servicio de alimentos),  
otro\_\_\_\_\_
- 4 Otro\_\_\_\_\_

7. ¿Cuál es su edad? \_\_\_\_\_

8. ¿Asistió a la escuela? Si así fue, ¿Cuántos años de escuela completó?

**Grado** 1 2 3 4 5 6 7 8 9 10 11 12

**Universidad** 1 2 3 4 5

**Postgrado** 1 2 3 4 5+

9. ¿Hace cuánto tiempo le fue diagnosticado que tiene diabetes?

\_\_\_\_\_años \_\_\_\_\_ meses \_\_\_\_\_

10. ¿Cuándo fue su último examen de la vista?

- 1 hace menos de un año
- 2 entre 1-2 años
- 3 hace más de 2 años
- 4 Otro\_\_\_\_\_
- 5 Nunca

11. ¿Cuándo fue su ultimo examen dental?

- 1 hace menos de un año
- 2 entre 1-2 años
- 3 hace más de 2 años
- 4 Otro\_\_\_\_\_
- 5 Nunca

12. ¿Qué tipo de medicinas para la diabetes está tomando?

- |  |   |
|--|---|
| 1 Ninguna  | 4 Insulina y píldoras,<br>pastillas o cápsulas<br>que ingiere |
| 2 Píldoras, pastillas, o cápsulas<br>que ingiere | 5 Bomba de insulina   |
| 3 Insulina                                       |   |

13. ¿Fuma usted?      Sí      No; si contestó **Sí**, ¿Cuántos cigarillos  
en una semana? \_\_\_\_\_

14. **Para llenar por el entrevistador** – altura actual:

\_\_\_\_\_ pies \_\_\_\_\_ pulgadas

15. **Para llenar por el entrevistador** – peso actual: \_\_\_\_\_ lbs.

16. **Para llenar por el entrevistador** - Presión arterial: \_\_\_\_\_

17. **Para llenar por el entrevistador** – Circunferencia de la cintura:  
\_\_\_\_\_ pulgadas

## II. Salud física

**Por favor conteste las siguientes preguntas con base en su situación actual.**

1. ¿Podría usted decir que su estado general de salud es:

- |             |           |
|-------------|-----------|
| 1 Excelente | 4 Regular |
| 2 Muy bueno | 5 Malo    |
| 3 Bueno     |           |

2. ¿Le ha dicho su médico alguna vez que usted tiene alguna de las siguientes enfermedades?

No      Sí

a. Artritis	0	1
-------------	---	---

b. Asma, bronquitis	0	1
Si contestó <b>Sí</b> , ¿cuándo? _____		

c. Alta presión arterial (hipertensión)	0	1
---	---	---

d. Úlceras Si contestó <b>Sí</b> , ¿Cuándo?_____	0	1
e. Problemas de la vista (además del uso de lentes) Si contestó <b>Sí</b> , ¿Cuándo?_____	0	1
f. Enfermedad de los riñones	0	1
g. Cáncer o leucemia	0	1
h. Desórdenes de la tiroides o de otras glándulas	0	1
i. Problemas crónicos de la espalda	0	1
j. Amputaciones debido a complicaciones por la diabetes	0	1
k. Condición del corazón, (por ejemplo, dolor en el pecho, latidos anormales, ataque)	0	1
l. Colesterol alto	0	1
m. Triglicéridos altos	0	1
n. Otra(s) <i>(Nombre(s) de la(s) enfermedad(es))</i> _____	0	1
3. ¿Tiene un médico de cabecera?	0	1



### III. Cuidado personal/Actividad física/dieta

Las siguientes preguntas se refieren a las actividades de su cuidado personal acerca de su diabetes durante los 7 días pasados. Si estuvo enfermo durante los últimos 7 días, por favor recuerde los 7 últimos días que **no** estuvo enfermo.

¿Cuánto tiempo **total** (en la semana **entera**) pasa usted en las siguientes actividades?

- |  |   |
|--|---|
| 1. ¿Ejercicios de estiramiento o de fortalecimiento (rango de movimiento, uso de pesas, etc.)? | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
|--|---|

- |                                  |   |
|----------------------------------|---|
| 2. ¿Camina para hacer ejercicio? | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
|----------------------------------|---|

- |                                      |   |
|--------------------------------------|---|
| 3. ¿Natación o ejercicios acuáticos? | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
|--------------------------------------|---|

- |  |   |
|--|---|
| 4. ¿Ciclismo (incluyendo bicicletas estacionarias para ejercicio)? | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
|--|---|

5. ¿Otros ejercicios aeróbicos con máquinas (escalones, remos, esquís, etc.)?
- 0 Nada  
1 Menos de 30 minutos por semana  
2 30 a 60 minutos por semana  
3 1 a 3 horas por semana  
4 Más de 3 horas por semana

6. Otros ejercicios aeróbicos?  
Por favor haga una lista
- \_\_\_\_\_
- \_\_\_\_\_
- 0 Nada  
1 Menos de 30 minutos por semana  
2 30 a 60 minutos por semana  
3 1 a 3 horas por semana  
4 Más de 3 horas por semana

¿Cuántos días durante la semana pasada hizo usted lo siguiente:

Número de días

- |  |        |        |        |   |   |
|--|--------|--------|--------|---|---|
| 7. Participó en por lo menos un total de 30 minutos de actividad física? (otra actividad además de la desarrollada durante su trabajo) | 0<br>5 | 1<br>6 | 2<br>7 | 3 | 4 |
|--|--------|--------|--------|---|---|

- |   |        |        |        |   |   |
|---|--------|--------|--------|---|---|
| 8. ¿Revisó si tiene llagas en los pies? | 0<br>5 | 1<br>6 | 2<br>7 | 3 | 4 |
|---|--------|--------|--------|---|---|

- |  |        |        |        |   |   |
|--|--------|--------|--------|---|---|
| 9. ¿Vigiló/controló la glucosa en su sangre? | 0<br>5 | 1<br>6 | 2<br>7 | 3 | 4 |
|--|--------|--------|--------|---|---|

10. ¿Tiene un plan de alimentación para diabéticos?
- Sí                  No

- Si contestó **Sí**, ¿Cuántos días lo ha seguido durante la semana pasada?
- |        |        |        |   |   |
|--------|--------|--------|---|---|
| 0<br>5 | 1<br>6 | 2<br>7 | 3 | 4 |
|--------|--------|--------|---|---|

11. ¿Está tomando medicinas para la diabetes?      Sí      No

Si contestó **Sí**:

¿Cuál medicina está tomando? \_\_\_\_\_

¿Cuál es la dosis? \_\_\_\_\_

¿Con qué frecuencia la toma?

- 1 Menos de 1 vez al día
- 2 1 vez al día
- 3 2 veces al día
- 4 más de 2 veces al día

12. ¿Ha estado usted incapacitado para tomar su medicina en los últimos 3 meses?      Sí      No

Si contestó **Sí**, ¿Cuántos días estuvo usted incapacitado para tomar su medicina?

- 1 2 días
- 2 1 semana
- 3 4 semanas
- 4 Otro tiempo \_\_\_\_\_

¿Por qué estuvo incapacitado para tomar su medicina? \_\_\_\_\_

#### IV. Recursos de ayuda

Las siguientes preguntas son acerca de diferentes recursos que las personas pueden usar para controlar su enfermedad. Para cada asunto, indique la caja que mejor representa sus experiencias durante el pasado año.

<b>Durante el pasado año:</b>	<u>No</u>	<u>Sí</u>
1. ¿Le ha explicado su médico los resultados de los exámenes que usted se ha hecho (por ejemplo: colesterol, presión arterial, A1c)?	0	1
2. ¿Entendió usted los resultados?	0	1

3. ¿Ha tenido usted un seguro de salud para cubrir la mayoría de los costos de sus necesidades médicas incluyendo medicinas?

0      1

4. ¿Ha asistido a reuniones gratis o de bajo costo que lo han ayudado en el control de su diabetes?

0      1

Si contestó que **Sí**, ¿a cuáles ha asistido? \_\_\_\_\_

5. ¿Ha utilizado usted las facilidades de gimnasios (por ejemplo, YMCA, curves, 24 Hour Fitness, clubes locales de salud/deporte?

0      1

Si contestó **Sí**, ¿Adónde ha ido? \_\_\_\_\_

Si no, ¿Por qué no? \_\_\_\_\_
















6. ¿Normalmente tiene usted una persona de apoyo (por ejemplo, un miembro de la familia o un amigo(a)) que lo ayuda a controlar su diabetes?

0      1

Si contestó que **Sí**, ¿Cuál es la relación?      miembro de la familia  
amigo(a)

## V. Autoconfiable para la diabetes

Nos gustaría saber qué tan seguro es usted haciendo ciertas actividades. Para cada una de las siguientes preguntas, por favor circule la carita que corresponda a **su** seguridad de que usted puede cumplir al presente con estas tareas en forma regular.

	<u>NO SEGURO</u>	<u>ALGO SEGURO</u>	<u>SEGURO</u>
1. ¿Qué tan seguro se siente de que puede seguir su plan alimenticio especial de diabetes?			
2. ¿Qué tan seguro se siente de que puede seguir su dieta cuando tenga que preparar o compartir alimentos con otras personas que <b>no</b> tienen diabetes?			
3. ¿Qué tan seguro se siente de que puede escoger los alimentos apropiados cuando tiene hambre (Por ejemplo, refrigerios)?			
4. ¿Qué tan seguro se siente de que puede hacer ejercicios de 15 a 30 minutos, 4 a 5 veces por semana?			
5. ¿Qué tan seguro se siente de que puede hacer algo para prevenir que baje el nivel de azúcar en su sangre cuando usted hace ejercicios?			

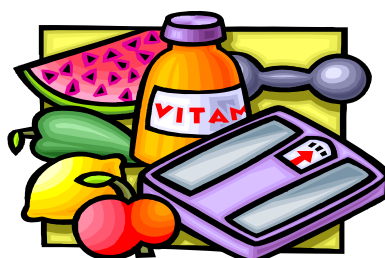
**USTED HA COMPLETADO ESTA ENCUESTA. ¡GRACIAS!**

### Appendix 3

Hispanic Family Diabetes Project Follow up Questionnaire – for participant with diabetes  
(English and Spanish)

# Hispanic Family Diabetes Project

Follow up Questionnaire  
(Participant with diabetes)



This questionnaire is part of a project to learn how diet and physical activity can affect diabetes management. These questions should be easy for you to answer, and you shouldn't spend too much time on each one. **There are no right or wrong answers.**

Your answers are very important for this project. Please try not to skip questions unless the questionnaire tells you to do so. However, you are free to skip any questions that you would prefer not to answer.

If you have questions about any of the items, please feel free to ask project staff for help.

Office Use Only

Participant ID #:

DATE

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

Site:

## I. Participant Information

Please answer the following questions based on your present situation.

1. What is your present living arrangement?

- |                               |   |
|-------------------------------|---|
| 1 Live with spouse or partner | 4 Live with spouse/partner and children |
| 2 Live with other relatives   | 5 Live with unrelated roommates         |
| 3 Live with children only     | 6 Live alone                            |

2. Where do you currently live?

- 1 In my own home
- 2 In an apartment or other rental
- 3 In a relative's home
- 4 Other\_\_\_\_\_

3. What is your current marital status?

- |             |                           |
|-------------|---------------------------|
| 1 Married   | 4 Divorced                |
| 2 Widowed   | 5 Never married or single |
| 3 Separated |                           |

4. Which of the following describes your work status?

- 1 Work, full-time
- 2 Work, part-time\_\_\_\_\_ (hours/week)
- 3 Not working
- 4 Retired (not working)
- 5 Homemaker



5. If you work outside the home, what type of work do you do?
- 1 Manual labor (construction, farm work), other \_\_\_\_\_
  - 2 Desk job/office worker
  - 3 Service industry (clerk, food service), other \_\_\_\_\_
  - 4 Other \_\_\_\_\_
6. What is your age? \_\_\_\_\_
7. What type of diabetes medication are you taking now?
- |   |  |
|---|--|
| 1 None  | 4 Insulin and pills,<br>tablets, or capsules<br>that you swallow |
| 2 Pills, tablets, or capsules<br>that you swallow | 5 Insulin pump   |
| 3 Insulin   |  |
8. Do you smoke?      Yes      No;    if Yes, how many cigarettes in  
one week? \_\_\_\_\_
9. **Interviewer to fill in** - present weight: \_\_\_\_\_ lbs.
10. **Interviewer to fill in** - blood pressure: \_\_\_\_\_
11. **Interviewer to fill in** – waist circumference: \_\_\_\_\_  
inches

## II. Physical Health

Please answer the following questions based on your present situation.

1. Would you say your health in general is:
- |             |        |
|-------------|--------|
| 1 Excellent | 4 Fair |
| 2 Very Good | 5 Poor |
| 3 Good      |        |
2. In the past 3 months, has a doctor told you that you have any of the following?

	<u>No</u>	<u>Yes</u>
a. Arthritis	0	1
b. Asthma, bronchitis If yes, when?_____	0	1
c. High blood pressure (hypertension)	0	1
d. Ulcers If yes, when?_____	0	1
e. Vision problems (besides wearing glasses) If yes, when?_____	0	1
f. Kidney disease	0	1
g. Cancer or leukemia	0	1
h. Thyroid or other glandular disorders	0	1
i. Chronic back problems	0	1
j. Amputations due to diabetes complications	0	1
k. Heart condition (e.g., chest pains, abnormal heart beats, heart attack)	0	1
l. High cholesterol	0	1
m. High triglycerides	0	1
n. Other ( <i>Name illness(es)</i> _____)	0	1
3. Do you have a health care provider ?	0	1

### III. Self Care/Physical Activity/Diet

The following questions ask about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

How much **total** time (for **entire** week) did you spend on each of the following?

- |  |   |
|--|---|
| 1. Stretching or strengthening exercises (range of motion, using weights, etc.)? | 0 None<br>1 Less than 30 minutes per week<br>2 30 to 60 minutes per week<br>3 1 to 3 hours per week<br>4 More than 3 hours per week |
|--|---|

- |                            |   |
|----------------------------|---|
| 2. Walk/hike for exercise? | 0 None<br>1 Less than 30 minutes per week<br>2 30 to 60 minutes per week<br>3 1 to 3 hours per week<br>4 More than 3 hours per week |
|----------------------------|---|

- |                                  |   |
|----------------------------------|---|
| 3. Swimming or aquatic exercise? | 0 None<br>1 Less than 30 minutes per week<br>2 30 to 60 minutes per week<br>3 1 to 3 hours per week<br>4 More than 3 hours per week |
|----------------------------------|---|

4. Bicycling (including stationary exercise bikes)?	0 None 1 Less than 30 minutes per week 2 30 to 60 minutes per week 3 1 to 3 hours per week 4 More than 3 hours per week
5. Other aerobic exercise equipment (Stairmaster, rowing, skiing machine, etc.)?	0 None 1 Less than 30 minutes per week 2 30 to 60 minutes per week 3 1 to 3 hours per week 4 More than 3 hours per week
6. Other aerobic exercise? Please list _____ _____	0 None 1 Less than 30 minutes per week 2 30 to 60 minutes per week 3 1 to 3 hours per week 4 More than 3 hours per week

How many days during the past week did you:

**Number of Days**

7. Participate in at least 30 minutes total of physical activity? (other than activity performed during your work?)	0	1	2	3	4
	5	6	7		
8. Check your feet for sores?	0	1	2	3	4
	5	6	7		
9. Monitor your blood glucose?	0	1	2	3	4
	5	6	7		

10. Do you have a diabetes meal plan?      Yes      No

If yes, how many days have you followed it in the last week?

0	1	2	3	4
5	6	7		

11. Are you taking medication for diabetes?      Yes      No

If yes:

What medication are you taking?

---

What is the dosage?

---

How frequently do you take it?

- 1 less than 1 time per day
- 2 1 time per day
- 3 2 times per day
- 4 more than 2 times per day

12. Have you been unable to take your medication in the last 3 months?      Yes      No

If yes, how many days were you unable to take your medication?

- 1 2 days
- 2 1 week
- 3 4 weeks
- 4 Other \_\_\_\_\_

Why were you unable to take your medication?

---
















#### IV. Supportive Resources

The following questions ask about a variety of different resources that people may use to manage their illness. For each item, check the box that best indicates your experiences over the past 3 months.

Over the past 3 months:	<u>No</u>	<u>Yes</u>
1. Has your doctor explained the results of tests you had done (e.g., cholesterol, blood pressure, A1c)?	0	1
2. Did you understand the results?	0	1
3. Have you had health insurance that covered most of the costs of your medical needs including medicine?	0	1
4. Have you utilized fitness facilities (e.g., YMCA, Curves, 24 hr fitness, local health/sports clubs)?	0	1
If yes, where did you go?	<hr/>	
If no, why not?	<hr/>	
5. Has your social support person helped you to manage your diabetes?	0	1

#### V. Self-Confidence for Diabetes
















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

	<u>NOT</u> <u>CONFIDENT</u>	<u>SOMEWHAT</u> <u>CONFIDENT</u>	<u>CONFIDENT</u>
1. How confident do you feel that you can follow your diabetes meal plan?			
2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?			
3. How confident do you feel that you can choose appropriate foods to eat when you are hungry (for example, snacks)?			
4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?			
5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?			

## **VI. Hispanic Family Diabetes Education Program *Evaluation***

The following questions ask about your experiences with the education program you just completed. For each item, circle the face that best describes your experiences with the program.

How satisfied have you been with...:

	<u>NOT</u> <u>SATISFIED</u>	<u>MODERATELY</u> <u>SATISFIED</u>	<u>SATISFIED</u>
1. The overall program?			
2. The program leader(s)?			
3. Guest presenters' knowledge and skills?			
4. The handouts and other written materials you received?			
5. The amount of contact and support you received?			

**Over the past 10 weeks, did the education program help you...:**

	<u>No</u>	<u>Yes</u>
1. Achieve your personal goals with diet?	0	1
2. Achieve your personal goals with exercise?	0	1
3. Communicate better with your health care provider?	0	1
4. Use community resources?	0	1
5. Manage your diabetes, including blood sugar, medication, and diet?	0	1



Was the program offered...:                      No      Yes

1. At a convenient time?                      0              1

2. In a convenient location?                      0              1

3. In an accessible room?                      0              1

4. In a comfortable room?                      0              1

In your own words tell us what you think about the education program.

1. What did you like **BEST**?

2. What did you like **LEAST**?

3. What suggestions do you have for improving the program?

4. Would you recommend this program to others?              Yes              No

5. Would you be willing to meet again at a later date so that results of this project can be reviewed?              Yes              No

6. Would you be willing to be contacted by us in the future to determine how you are managing your diabetes?      Yes      No

7. If yes, please provide us with your contact information:

Name \_\_\_\_\_

Mailing Address \_\_\_\_\_

\_\_\_\_\_

Phone \_\_\_\_\_

Best day/evening to call: \_\_\_\_\_

E-mail \_\_\_\_\_

You have completed this survey. Thank you!

# Proyecto Investigación de Diabetes en la Familia Hispana

Cuestionario de seguimiento  
(*Participante con diabetes*)



Este cuestionario es parte de un proyecto para aprender cómo la dieta y la actividad física pueden afectar el control de la diabetes. Estas preguntas son muy fáciles de contestar y usted no debería tomar mucho tiempo para contestar cada una. **No hay respuestas correctas ni incorrectas.**

Sus respuestas son muy importantes para este proyecto. Por favor trate de no saltarse preguntas a menos que se lo indique el cuestionario. Sin embargo, siéntase en libertad de no contestar algunas preguntas si usted prefiere no hacerlo.

Si tiene preguntas acerca de algo, por favor siéntase en libertad de pedir ayuda al personal del proyecto.

Office Use Only

Participant ID #:

DATE

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

Site:

## I. Información del participante

Por favor conteste las siguientes preguntas con base en su situación actual.

1. ¿Cuál es su arreglo actual de vivienda?

- |                                     |   |
|-------------------------------------|---|
| 1 Vive con esposo(a) o compañero(a) | 4 Vive con esposo(a)/compañero(a) y con los hijos |
| 2 Vive con otros parientes          |   |
|                                     | 5 Vive con personas no parientes                  |
| 3 Vive con los hijos solamente      | 6 Vive solo(a)                                    |

2. ¿Dónde vive normalmente?

- 1 En mi propia casa
- 2 En un apartamento /otro lugar que alquila
- 3 En la casa de un pariente
- 4 Otro\_\_\_\_\_

3. ¿Cuál es su estado civil actual?

- |               |                                    |
|---------------|------------------------------------|
| 1 Casado(a)   | 4 Divorciado(a)                    |
| 2 Viudo (a)   | 5 Soltero(a). (Nunca se ha casado) |
| 3 Separado(a) |                                    |

4. ¿Cuál de las siguientes situaciones describe su estado de trabajo?

- 1 Trabaja, tiempo completo
- 2 Trabaja, tiempo parcial \_\_\_\_\_(horas por semana)
- 3 No trabaja
- 4 Retirado(a) (no trabaja)
- 5 Ama de casa

5. Si trabaja fuera de casa, ¿Qué tipo de trabajo realiza?
- 1 Trabajo físico (en construcción, en el campo), otro\_\_\_\_\_
  - 2 Trabajo de escritorio/oficinista
  - 3 Industria de servicio (dependiente, servicio de alimentos), otro\_\_\_\_\_
  - 4 Otro\_\_\_\_\_

6. ¿Cuál es su edad? \_\_\_\_\_

7. ¿Qué tipo de medicinas para la diabetes está tomando?

- |   |   |
|---|---|
| 1 Ninguna                                     | 4 Insulina y píldoras, pastillas o cápsulas que ingiere |
| 2 Píldoras, pastillas, o cápsulas que ingiere |   |
| 3 Insulina                                    | 5 Bomba de insulina                                     |

8. ¿Usted fuma?      Sí      No; Si contestó **Sí**, ¿Cuántos cigarillos en una semana?

\_\_\_\_\_

9. **Para llenar por el entrevistador** – peso actual: \_\_\_\_\_lbs.

10. **Para llenar por el entrevistador** - Presión arterial: \_\_\_\_\_

11. **Para llenar por el entrevistador** – Circunferencia de la cintura: \_\_\_\_\_ pulgadas

## II. Salud física

Por favor conteste las siguientes preguntas con base en su situación actual.

1. ¿Podría usted decir que su estado general de salud es:
- |             |           |
|-------------|-----------|
| 1 Excelente | 4 Regular |
| 2 Muy bueno | 5 Malo    |
| 3 Bueno     |           |

3. En los 3 meses pasados, ¿le ha dicho un médico que usted tiene cualquiera de las siguientes enfermedades:

	<u>No</u>	<u>Sí</u>
a. Artritis	0	1
b. Asma, bronquitis Si contestó <b>Sí</b> , ¿cuándo?_____	0	1
c. Alta presión arterial (hipertensión)	0	1
d. Úlceras Si contestó <b>Sí</b> , ¿Cuándo?_____	0	1
e. Problemas de la vista (además del uso de lentes) Si contestó <b>Sí</b> , ¿Cuándo?_____	0	1
f. Enfermedad de los riñones	0	1
g. Cáncer o leucemia	0	1
h. Desórdenes de la tiroides o de otras glándulas	0	1
i. Problemas crónicos de la espalda	0	1
j. Amputaciones debido a complicaciones por la diabetes	0	1
k. Condición del corazón, (por ejemplo, dolor en el pecho, latidos anormales, ataque)	0	1
l. Colesterol alto	0	1
m. Triglicéridos altos	0	1
n. Otra(s) <i>(Nombre(s) de la(s) enfermedad(es))</i> _____	0	1

3. ¿Tiene un médico de cabecera? 0 1

### III. Cuidado personal/Actividad física/dieta

Las siguientes preguntas se refieren a las actividades de su cuidado personal acerca de su diabetes durante los 7 días pasados. Si estuvo enfermo durante los últimos 7 días, por favor recuerde los 7 últimos días que **no** estuvo enfermo.

¿Cuánto tiempo **total** (en la semana **entera**) pasa usted en las siguientes actividades?

- |  |   |
|--|---|
| 1. ¿Ejercicios de estiramiento o de fortalecimiento (rango de movimiento, uso de pesas, etc.)? | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
| 2. ¿Camina para hacer ejercicio?   | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
| 3. ¿Natación o ejercicios acuáticos?   | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |
| 4. ¿Ciclismo (incluyendo bicicletas estacionarias para ejercicio)?                             | 0 Nada<br>1 Menos de 30 minutos por semana<br>2 30 a 60 minutos por semana<br>3 1 a 3 horas por semana<br>4 Más de 3 horas por semana |

5. ¿Otros ejercicios aeróbicos con máquinas (escalones, remos, esquís, etc.)?	0 Nada
	1 Menos de 30 minutos por semana
	2 30 a 60 minutos por semana
	3 1 a 3 horas por semana
	4 Más de 3 horas por semana
6. Otros ejercicios aeróbicos? Por favor haga una lista	0 Nada
_____	1 Menos de 30 minutos por semana
_____	2 30 a 60 minutos por semana
	3 1 a 3 horas por semana
	4 Más de 3 horas por semana

¿Cuántos días durante la semana pasada hizo usted lo siguiente:

### Número de días

	0	1	2	3	4
7. Participó en por lo menos un total de 30 minutos de actividad física? (otra actividad además de la desarrollada durante su trabajo)	5	6	7		
8. ¿Revisó si tiene llagas en los pies?	5	6	7		
9. ¿Vigiló/controló la glucosa en su sangre?	5	6	7		
10. ¿Tiene un plan de alimentación para diabéticos?					
Sí No					
Si contestó <b>Sí</b> , ¿Cuántos días lo ha seguido durante la semana pasada?	5	6	7		



11. ¿Está tomando medicinas para la diabetes?    Sí    No

Si contestó **Sí**:

¿Cuál medicina está tomando? \_\_\_\_\_

¿Cuál es la dosis? \_\_\_\_\_

¿Con qué frecuencia la toma?

- 1 Menos de 1 vez al día
- 2 1 vez al día
- 3 2 veces al día
- 4 más de 2 veces al día

12. ¿Ha estado usted incapacitado para tomar su medicina en los últimos 3 meses?    Sí    No

Si contestó **Sí**, ¿Cuántos días estuvo usted incapacitado para tomar su medicina?

- 1 2 días
- 2 1 semana
- 3 4 semanas
- 4 Otro tiempo \_\_\_\_\_

¿Por qué estuvo incapacitado para tomar su medicina?

\_\_\_\_\_

#### IV. Recursos de ayuda

Las siguientes preguntas son acerca de diferentes recursos que las personas pueden usar para controlar su enfermedad. Para cada asunto, indique la caja que mejor representa sus experiencias durante los 3 meses pasados.

En los 3 meses pasados:

No    Sí

1. ¿Le ha explicado su médico los resultados de los exámenes que usted se ha hecho (por ejemplo: colesterol, presión arterial, A1c)?

0       1

2. ¿Entendió usted los resultados?

0       1

3. ¿Tenía usted un seguro de salud para cubrir la mayoría de los costos de sus necesidades médicas incluyendo medicinas?

0       1

4. ¿Ha utilizado usted las facilidades de gimnasios (por ejemplo, YMCA, Curves, 24 Hour Fitness, clubes locales de salud/deporte?

0       1
















Si contestó **Sí**, ¿Adónde fue?  
Si contestó **No**, ¿Por qué no?

5. ¿Le ha ayudado a controlar su diabetes la persona que lo apoya?

0       1

## V. Autoconfidente para la diabetes
















Nos gustaría saber qué tan seguro es usted haciendo ciertas actividades. Para cada una de las siguientes preguntas, por favor circule la carita que corresponda a **su** seguridad de que usted puede cumplir al presente con estas tareas en forma regular.

	<b>NO SEGURO</b>	<b>ALGO SEGURO</b>	<b>SEGURO</b>
1. ¿Qué tan seguro se siente de que puede seguir su plan alimenticio especial de diabetes?			
2. ¿Qué tan seguro se siente de que puede seguir su dieta cuando tenga que preparar o compartir alimentos con otras personas que no tienen diabetes?			
3. ¿Qué tan seguro se siente de que puede escoger los alimentos apropiados cuando tiene hambre (por ejemplo, refrigerios)?			
4. ¿Qué tan seguro se siente de que puede hacer ejercicios de 15 a 30 minutos, 4 a 5 veces por semana?			
5. ¿Qué tan seguro se siente de que puede hacer algo para prevenir que baje el nivel de azúcar en su sangre cuando usted hace ejercicios?			

## **VI. Evaluación del Programa de Educación sobre Diabetes en la Familia Hispana**

Las siguientes preguntas son acerca de sus experiencias con el programa de educación que usted ha completado. Para cada asunto, circule la carita que mejor refleje sus experiencias

¿Qué tan satisfecho ha estado usted con...:

	NO SATISFECHO	MODERADAMENTE SATISFECHO	SATISFECHO
1. Todo el programa?			
2. Los líderes del programa?			
3. El conocimiento y habilidades de los presentadores invitados?			
4. Los folletos y otros materiales escritos que recibió?			
5. El contacto y apoyo que recibió?			

Durante las 10 semanas pasadas, ¿le ayudó el programa de educación a...:

	No	Sí
1. Alcanzar sus metas personales con dieta?	0	1
2. Alcanzar sus metas personales con ejercicio?	0	1
3. Comunicarse mejor con su médico?	0	1
4. Usar los recursos de la comunidad?	0	1

5. Controlar su diabetes, incluyendo azúcar en la sangre, medicina, y dieta?	0	1
---	---	---

El programa fue ofrecido...:

No    Sí

1. ¿A una hora conveniente?	0	1
-----------------------------	---	---

2. ¿En una localidad conveniente?	0	1
-----------------------------------	---	---

3. ¿En un salón accesible?	0	1
----------------------------	---	---

4. ¿En un salón cómodo?	0	1
-------------------------	---	---

Por favor díganos en sus propias palabras qué es lo que  
piensa acerca del programa de educación..

1. ¿Qué es lo que **más** le gustó?

2. ¿Qué es lo que **menos** le gustó?

3. ¿Qué sugerencias tiene para mejorar el programa?

4. ¿Les recomendaría este programa a otras personas?	Sí	No
--	----	----

5. ¿Estaría dispuesto a regresar en una fecha posterior para que los resultados de este proyecto sean revisados?	Sí	No
--	----	----

6. ¿Estaría dispuesto a que nos comuniquemos con usted en el futuro para determinar cómo está controlando su diabetes? Sí      No

7. Si contestó **Sí**, por favor provéanos la siguiente información:

Nombre \_\_\_\_\_

Dirección Postal \_\_\_\_\_

\_\_\_\_\_

Teléfono \_\_\_\_\_

El mejor día para llamarlo: \_\_\_\_\_ Hora: \_\_\_\_\_

Dirección electrónica:

\_\_\_\_\_@\_\_\_\_\_

Usted ha completado esta encuesta. ¡Gracias!

#### Appendix 4

Hispanic Family Diabetes Project Enrollment Questionnaire – for support participant  
(English and Spanish)

# Hispanic Family Diabetes Project

## Enrollment Questionnaire (Support participant)



This questionnaire is part of a project to learn how diet and physical activity can affect diabetes management. These questions should be easy for you to answer, and you shouldn't spend too much time on each one. **There are no right or wrong answers.**

Your answers are very important for this project. Please try not to skip questions unless the questionnaire tells you to do so. However, you are free to skip any questions that you would prefer not to answer.

If you have questions about any of the items, please feel free to ask project staff for help.

Office Use Only

Participant ID #:

DATE

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

Site:



## I. Participant Information

Please answer the following questions based on your present situation.

1. Are you male or female?

1 Male

2 Female

2. What is your age? \_\_\_\_\_

3. Were you able to attend school? If yes, how many years of school did you complete?

**Grade** 1 2 3 4 5 6 7 8 9 10 11 12

**College** 1 2 3 4 5

**Graduate School** 1 2 3 4 5+

4. What do you consider yourself to be?

1 Hispanic/Latino

2 American Indian or Alaska Native

3 Asian

4 Black or African American

5 Native Hawaiian or other Pacific Islander

6 White

7 More than one race

(please specify the race with which you identify **most**:

\_\_\_\_\_ )

8 Other (please specify: \_\_\_\_\_ )

5. What is your relationship to the person you are supporting that has diabetes?

1 Family member

2 Friend

6. How long have you known him/her? \_\_\_\_\_ (years)

7. Are you currently supporting your partner with diabetes in managing his/her disease? Yes No

8. If yes, how? Check all that apply:

- 1 Helping with diabetic meal planning, explain:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- 2 Helping with medication reminders
- 3 Exercising with partner that has diabetes, explain:  
what type of exercise\_\_\_\_\_
- how many times per week\_\_\_\_\_
- how many minutes per session\_\_\_\_\_
- 4 Reminding partner with diabetes to visit their health care professional
- 5 Reminding partner with diabetes to check their feet for sores
- 6 Reminding partner with diabetes to test their blood sugar

You have completed this survey. Thank you!

# Proyecto Investigación de Diabetes en la Familia Hispana

Cuestionario de inscripción  
(*Participante de apoyo*)



Este cuestionario es parte de un proyecto para aprender cómo la dieta y la actividad física pueden afectar el control de la diabetes. Estas preguntas son muy fáciles de contestar y usted no debería tomar mucho tiempo para contestar cada una. **No hay respuestas correctas ni incorrectas.**

Sus respuestas son muy importantes para este proyecto. Por favor trate de no saltarse preguntas a menos que se lo indique el cuestionario. Sin embargo, siéntase en libertad de no contestar algunas preguntas si usted prefiere no hacerlo.

Si tiene preguntas acerca de algo, por favor siéntase en libertad de pedir ayuda al personal del proyecto.

Office Use Only

Participant ID #:

DATE

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

Site:

## I. Información del participante

Por favor conteste las siguientes preguntas con base en su situación actual.

1. ¿Es usted hombre o mujer?

1 Hombre

2 Mujer

2. ¿Cuál es su edad? \_\_\_\_\_

3. ¿Asistió usted a la escuela? Si así fue, ¿Cuántos años de escuela completó?

**Grado** 1    2    3    4    5    6    7    8    9    10    11    12

**Universidad**    1    2    3    4    5

**Postgrado**    1    2    3    4    5+

4. ¿Es usted:

1 Hispano(a)Latino(a)?

2 Indio(a) americano(a) o nativo(a) de Alaska

3 Asiático(a)

4 Negro(a) o Afroamericano(a)

5 Nativo(a) de Hawaii o de otras islas del Pacífico

6 Blanco(a)

7 Más de una raza

(Por favor especifique la raza con la cual usted se identifica **más**):

8 Otra (por favor especifique): \_\_\_\_\_

5. ¿Cuál es su relación con la persona a la que usted apoya y que tiene diabetes?

1 Miembro de la familia

2 Amigo(a)

6. ¿Hace cuánto tiempo lo (la) conoce? \_\_\_\_\_ (años) \_\_\_\_\_ (meses)

7. ¿Está usted normalmene apoyando a su compañero(a) con diabetes en el control de su enfermedad?

Sí

No

8. Si contesta **Sí**, ¿Cómo? Indique todo lo que se aplica:

- 1 Ayudándole a planear los alimentos para diabéticos.  
Explique:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- 2 Ayudándole a recordar sus medicinas
- 3 Haciendo ejercicios con el (la) compañero(a) que tiene diabetes. Explique:  
¿Qué tipo de ejercicio? \_\_\_\_\_  
¿Cuántas veces a la semana? \_\_\_\_\_  
¿Cuántos minutos por sesión? \_\_\_\_\_
- 4 Recordándole al (la) compañero(a) con diabetes que visite a su médico.
- 5 Recordándole al (la) compañero(a) con diabetes que observe sus si tiene llagas en los pies.
- 6 Recordándole al (la) compañero(a) con diabetes que se examine el azúcar en la sangre.

**Usted ha completado esta encuesta. ¡Gracias!**

## Appendix 5

Hispanic Family Diabetes Project Follow up Questionnaire – for support participant  
(English and Spanish)

# Hispanic Family Diabetes Project

Follow up Questionnaire  
(*Support Participant*)



This questionnaire is part of a project to learn how diet and physical activity can affect diabetes management. These questions should be easy for you to answer, and you shouldn't spend too much time on each one. **There are no right or wrong answers.**

Your answers are very important for this project. Please try not to skip questions unless the questionnaire tells you to do so. However, you are free to skip any questions that you would prefer not to answer.

If you have questions about any of the items, please feel free to ask project staff for help.

Office Use Only

Participant ID #:

DATE

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

Site:

## I. Participant Information

Please answer the following question based on your present situation.

1. How were you able to support your partner with diabetes during the education program that you just completed? Check all that apply:
















- 1 Helped with diabetic meal planning, explain:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- 2 Helped with medication reminders
- 3 Exercised with partner that has diabetes, explain:  
what type of exercise \_\_\_\_\_  
how many times per week \_\_\_\_\_  
how many minutes per session \_\_\_\_\_
- 4 Reminded partner with diabetes to visit their health care professional
- 5 Reminded partner with diabetes to check their feet for sores
- 6 Reminded partner with diabetes to test their blood sugar

## II. Hispanic Family Diabetes Education Program Evaluation

The following questions ask about your experiences with the education program you just completed. For each item, circle the face that best describes your experiences with the program.



How satisfied have you been with...: NOT MODERATELY  
SATISFIED SATISFIED SATISFIED

1. The overall program?			
2. The program leader(s)?			
3. Guest presenters' knowledge and skills?			
4. The handouts and other written materials you received?			
5. The amount of contact and support you received?			

Was the program offered...: No Yes

1. At a convenient time?	0	1
2. In a convenient location?	0	1
3. In an accessible room?	0	1
4. In a comfortable room?	0	1

In your own words tell us what you think about the education program.

1. What did you like **BEST**?

2. What did you like **LEAST**?

3. What suggestions do you have for improving the program?

4. Would you recommend this program to others?                      Yes      No

5. Would you be willing to meet again at a later date so that results of  
this project can be reviewed?    Yes      No

6. Would you be willing to be contacted by us in the future to  
determine how your role as support person is helping your partner  
with diabetes make healthy lifestyle changes?                      Yes      No

7. If yes, please provide us with your contact information:

Name \_\_\_\_\_

Mailing Address \_\_\_\_\_

\_\_\_\_\_

Phone \_\_\_\_\_

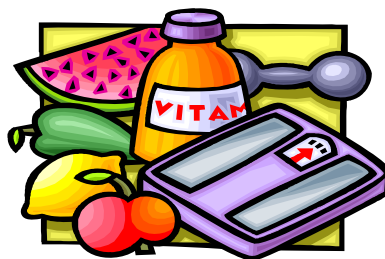
Best day/evening to call: \_\_\_\_\_

E-mail \_\_\_\_\_

You have completed this survey. Thank you!

# Proyecto Investigación de Diabetes en la Familia Hispana

Cuestionario de seguimiento  
(*Participante de apoyo*)



Este cuestionario es parte de un proyecto para aprender cómo la dieta y la actividad física pueden afectar el control de la diabetes. Estas preguntas son muy fáciles de contestar y usted no debería tomar mucho tiempo para contestar cada una. **No hay respuestas correctas ni incorrectas.**

Sus respuestas son muy importantes para este proyecto. Por favor trate de no saltarse preguntas a menos que se lo indique el cuestionario. Sin embargo, siéntase en libertad de no contestar algunas preguntas si usted prefiere no hacerlo.

Si tiene preguntas acerca de algo, por favor siéntase en libertad de pedir ayuda al personal del proyecto.

Office Use Only

Participant ID #:

DATE

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

Site:

## I. Información del participante

Por favor conteste las siguientes preguntas con base en su situación actual.

1. ¿De qué manera ha ayudado a su compañero(a) con diabetes durante el programa de educación que usted ha completado? Señale todo lo que se aplica:
















- 1 Lo he ayudado a planear sus alimentos. **Explique:**  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
- 2 Lo he ayudado recordándole sus medicinas
- 3 He realizado ejercicios físicos con él. **Explique:**  
 qué tipo de ejercicio \_\_\_\_\_  
 cuántas veces por semana \_\_\_\_\_  
 cuántos minutos por sesión \_\_\_\_\_
- 4 Le he recordado que visite a su médico
- 5 Le he recordado que examine sus pies por llagas
- 6 Le he recordado que examine el azúcar en su sangre

## II. Evaluación del Programa de Educación de la Diabetes en la Familia Hispana

Las siguientes preguntas se refieren a sus experiencias con el programa de educación que usted ha terminado. Para cada tema, circule la carita que mejor describa sus experiencias.

¿Qué tan satisfecho ha estado usted con...:

NO MODERADAMENTE  
SATISFECHO SATISFECHO SATISFECHO

1. Todo el programa?			
2. Los líderes del programa?			
3. Conocimiento y habilidades de los presentadores invitados?			
4. Los folletos y otros materiales escritos que recibió?			
5. El contacto y apoyo que recibió?			

El programa fue ofrecido:

No Sí

1. ¿A una hora conveniente?	0	1
2. ¿En una localidad conveniente?	0	1
3. ¿En un salón accesible?	0	1
4. ¿En un salón cómodo?	0	1

En sus propias palabras díganos qué piensa del programa de educación.

1. ¿Qué es lo que **más** le gustó?
  
  
  
  
  
  
  
  
  
  
2. ¿Qué es lo que **menos** le gustó?
  
  
  
  
  
  
  
  
  
  
3. ¿Qué nos puede sugerir para mejorar el programa?
  
  
  
  
  
  
  
  
  
  
4. ¿Recomendaría a otros este programa? Sí      No
  
  
  
  
  
  
  
  
  
  
5. ¿Estaría dispuesto a regresar en una fecha posterior para que los resultados de este proyecto sean revisados? Sí      No
  
  
  
  
  
  
  
  
  
  
6. ¿Estaría dispuesto para que nos comuniquemos con usted en el futuro para determinar cómo su papel de persona de apoyo está ayudando a su compañero con diabetes a hacer cambios en su estilo de vida? Sí      No
  
  
  
  
  
  
  
  
  
  
7. Si contestó Sí, por favor provéanos la siguiente información:

Nombre \_\_\_\_\_

Dirección postal \_\_\_\_\_

\_\_\_\_\_

Teléfono \_\_\_\_\_

El mejor día para llamarle: \_\_\_\_\_ Hora: \_\_\_\_\_

Dirección electrónica: \_\_\_\_\_@\_\_\_\_\_

Usted ha completado esta encuesta. ¡Gracias!



## Appendix 6

Recruitment flyer for each county (English and Spanish)

**Interested in learning more about your diabetes?**

Oregon State University, the State of Oregon, and Multnomah County are studying whether diabetes education for you and a support person can help in managing your diabetes. Benefits of participating include assessment of diet, physical activity level, blood work, and risk factors for diabetes.

**Research Title:** Hispanic Family Diabetes Project

**Wanted:** Hispanic volunteers with diabetes and their support person (for example, friend or family member) are being recruited to participate in this research study.

**Criteria:** Males or females 19 years or older.

**For more information about the study call:**

**Ruby Ibarra - (503) 988-3663 x 83991**

**Interested in learning more about your diabetes?**

Oregon State University, the State of Oregon, and Multnomah County are studying whether diabetes education for you and a support person can help in managing your diabetes. Benefits of participating include assessment of diet, physical activity level, blood work, and risk factors for diabetes.

**Research Title:** Hispanic Family Diabetes Project

**Wanted:** Hispanic volunteers with diabetes and their support person (for example, friend or family member) are being recruited to participate in this research study.

**Criteria:** Males or females 19 years or older.

**For more information about the study call:**

**Sandra Guerrero – (541) 308-8378 OR Joel Pelayo – (541) 386-4880**

## **¿ESTÁ INTERESADO EN APRENDER MÁS ACERCA DE SU DIABETES?**

La Universidad del Estado de Oregón, el Estado de Oregón y el Condado Multnomah están considerando si una educación sobre la diabetes para usted y la persona que lo apoya puede ayudarles a controlar su diabetes. Los beneficios por participar en este estudio de investigación incluyen: evaluación de dieta, nivel de actividad física, análisis de laboratorio, y factores de riesgo por diabetes.

**Título del proyecto:** Investigación de Diabetes en la Familia Hispana

**Se necesitan:** Voluntarios hispanos que padezcan de diabetes y la persona que los ayuda (por ejemplo, un amigo o un miembro de la familia) para que participen en este estudio de investigación.

**Requisitos:** Hombres y mujeres con edad mínima de 19 años.

**Para mayor información acerca del estudio llame a:**

**Ruby Ibarra - (503) 988-3663 x 83991**

## **¿ESTÁ INTERESADO EN APRENDER MÁS ACERCA DE SU DIABETES?**

La Universidad del Estado de Oregón, el Estado de Oregón y el Condado Multnomah están considerando si una educación sobre la diabetes para usted y la persona que lo apoya puede ayudarles a controlar su diabetes. Los beneficios por participar en este estudio de investigación incluyen: evaluación de dieta, nivel de actividad física, análisis de laboratorio, y factores de riesgo por diabetes.

**Título del proyecto:** Investigación de Diabetes en la Familia Hispana

**Se necesitan:** Voluntarios hispanos que padezcan de diabetes y la persona que los ayuda (por ejemplo, un amigo o un miembro de la familia) para que participen en este estudio de investigación.

**Requisitos:** Hombres y mujeres con edad mínima de 19 años.

**Para mayor información acerca del estudio llame a:**

**Sandra Guerrero – (541) 308-8378 O Joel Pelayo – (541) 386-4880**

## Appendix 7

Telephone/in person script for screening purposes (English and Spanish)

**Telephone/in person script for screening purposes:**

Volunteers calling or hearing about the study through the local clinics will be screened before making any commitments to this project:

Thank you for calling in response to our announcement. I need to learn more about you so I can determine if you will meet our criteria for this research study. This interview is anonymous and confidential. If we decide you fit the criteria for our study, we will set an appointment that is convenient for you to learn more about this study and being in this project.

Name \_\_\_\_\_ Today's Date \_\_\_\_\_

Phone \_\_\_\_\_ Mailing Address \_\_\_\_\_

Best day/evening to call: \_\_\_\_\_

E-mail \_\_\_\_\_

I need to ask you some personal questions, are you comfortable with this?  
Do you have about 3 minutes to answer some questions?

Gender: Male \_\_\_\_\_ Female \_\_\_\_\_

How old are you? \_\_\_\_\_

Are you Hispanic/Latino?

Yes \_\_\_\_\_ No \_\_\_\_\_

Have you been diagnosed with having diabetes by a physician? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, would you be willing to participate in a 12-week education program aimed at improving your risk factors for diabetes through nutrition, physical activity, and self-care?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, would you be able to recruit a support person (friend, family member) who would come with you to the education classes?

Yes \_\_\_\_\_ No \_\_\_\_\_

The information you have provided appears to fit our initial criteria. This project will require that you attend an education program at your local health clinic. This program

will last 12 weeks and will be offered 1 time per week. The first and last session will be \_\_\_\_\_ (day/time). Sessions 2-11 will be held \_\_\_\_\_ (day/time). (In Hood River these sessions have been scheduled for Saturday at 10 am). Each class will run about 60-90 minutes.

Attendance is strongly encouraged since each week a new topic will be discussed. Attendance for both you and your support person will be recorded every week.

At the first and last sessions you will need to fill out a couple of diet and health questionnaires. Blood will also be drawn from your arm (about 4 tablespoons) and your height, weight, blood pressure, and waist size will be taken. Sessions 2 through 11 will be devoted to the education program aimed at improving diet, physical activity, and diabetic self-care.

Do you have any further questions about this project?

**Alternative Closure:**

Thank you for your time, but I'm sorry, you don't seem to fit the criteria we are looking for in this project, but would you be willing to participate in another research project at OSU in the future?

Yes \_\_\_\_ No \_\_\_\_

**Guión telefónico para propósitos de selección:**

Los voluntarios que llamen o a los que se llamen por medio de las clínicas locales acerca del estudio serán seleccionados antes de hacer algún compromiso con este proyecto:

“Gracias por llamar en respuesta a nuestro anuncio. Necesitamos saber más acerca de usted para poder determinar si cumple con los requisitos para este estudio de investigación. Esta entrevista es anónima y confidencial. Si decidimos que usted cumple con los requisitos, arreglaremos una cita conveniente para que sepa más acerca de este estudio y sea parte de este proyecto.

Nombre \_\_\_\_\_ Fecha de hoy \_\_\_\_\_

Teléfono \_\_\_\_\_ Dirección postal \_\_\_\_\_

Mejor día y hora para llamarlo: \_\_\_\_\_

Dirección electrónica \_\_\_\_\_

Necesito hacerle algunas preguntas personales. ¿Se siente cómodo con esto?

¿Tiene 3 minutos para contestar algunas preguntas?

Sexo: Masculino \_\_\_\_\_ Femenino \_\_\_\_\_

¿Qué edad tiene usted? \_\_\_\_\_

¿Es usted hispano?

Sí \_\_\_\_\_ No \_\_\_\_\_

¿Ha sido diagnosticado por un médico que tiene usted diabetes? Sí \_\_\_\_\_ No \_\_\_\_\_

Si la respuesta es afirmativa: ¿Estaría de acuerdo en participar en un programa de educación con el objeto de mejorar sus factores de riesgo por diabetes por medio de nutrición, actividad física y propio cuidado personal?

Sí \_\_\_\_\_ No \_\_\_\_\_

Si la respuesta es afirmativa, ¿estaría dispuesto a traer a las clases de educación a una persona que lo ayude (amigo o miembro de la familia)?

Sí \_\_\_\_\_ No \_\_\_\_\_

La información que nos ha dado parece llenar los requisitos iniciales. Este proyecto requerirá que usted asista a un programa de educación en su clínica local de salud. Este programa durará 12 semanas y sera ofrecido una vez por semana. La primera y la última clase serán \_\_\_\_\_ (día y hora). Las clases de la 2a. a la 11a. serán \_\_\_\_\_ (día y hora). (En Hood River estas clases han sido programadas para los días sábados a las 10 am). Cada clase durará de 60 a 90 minutos.

La asistencia es de vital importancia ya que cada semana será discutido un nuevo tópico. Su asistencia y la de la persona que lo ayude será registrada cada semana.

En la primera y última clases necesitará contestar dos cuestionarios sobre dieta y salud. También se le extraerá sangre de uno de sus brazos (unas 4 cucharadas); se le medirá su altura y su cintura, se le tomará su peso y su presión arterial . Las clases de la 2a. a la 11a. estarán dedicadas al programa de educación enfocado a mejorar la dieta, actividad física y cuidado personal de la persona que padece diabetes.

¿Tiene algunas preguntas acerca de este proyecto?

#### **Cierre alternativo:**

“Gracias por su tiempo, pero lo sentimos mucho; usted no parece cumplir con los requisitos para este proyecto, pero ¿estaría dispuesto a participar en otro proyecto de investigación de la Universidad del Estado de Oregon en el futuro?”

Sí \_\_\_\_ No \_\_\_\_



## Appendix 8

Informed Consent Documents - for both the participant with diabetes and support participant in Hood River County (English and Spanish)



Nutrition and Food Management  
Oregon State University, 108 Milam Hall, Corvallis, Oregon 97331-5103  
T 541-737-3581 | F 541-737-8914

## INFORMED CONSENT DOCUMENT (Participant with diabetes)

**Project Title:** **Hispanic Family Diabetes Project**

**Investigators:** **Melinda M. Manore, Ph.D., R.D. & Bev White R.D., M.S.**  
**Department of Nutrition and Food Management**  
**Oregon State University**

**Contact persons from** **Joel Pelayo (Nuestra Comunidad Sana)**  
**Hood River County:** **Sandra Guerrero (La Clinica Del Carino)**

### PURPOSE

The purpose of this research study is to determine whether a diabetes education program, which includes a support person, can help in managing your diabetes. The education program will include information on diet, physical activity, and diabetic self-care. Our goal is that you will improve your diabetes risk factors (for example diet and physical activity) and your laboratory values (blood glucose, which means blood sugar, and insulin) following the education program. If successful, this program has the potential to improve your overall health and to be implemented in other counties in Oregon.

The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study or not. Please read the form carefully. You may ask any questions about the research, what you will be asked to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all of your questions have been answered, you can decide if you want to be in this study or not. This process is called "informed consent". You will be given a copy of this form for your records.

We are inviting you to participate in this research study because you are of Hispanic descent and have diabetes. In addition, you are at least 19 years or older. A minimum of 20 male and female diabetic Hispanics, ages 19 years and older will be recruited.

### PROCEDURES

If you agree to participate, you will need to visit the local health clinic in your county every Saturday at 10 am for 12 weeks, to attend an education program. Each session will last 60-90 minutes. This program will be taught in Spanish by a community health worker. Attendance is strongly encouraged since each week a new topic will be discussed. Attendance for both you and your social support person will be recorded. This education program will begin in February 2005.

OSU IRB Approval Date: 01-24-05
Approval Expiration Date: 01-23-06

The first and last sessions will involve answering 2 questionnaires (one related to diet and one related to general health status, physical activity, and self-care history; for example blood glucose monitoring, checking your feet regularly for sores, and how often you visit a doctor). In addition 1 blood sample will be obtained from your arm at a time when you have not eaten for several hours. We will also measure your height, weight, blood pressure, and waist size. Your blood will be studied for levels of glucose (sugar), insulin, HgbA1c (a chemical marker for diabetes), and lipids (for example, cholesterol). You will not be notified of your laboratory results until the end of the study unless the results are highly abnormal. If the results are highly abnormal, you will be notified and a copy of the results will be sent to your physician. At this point, you will be encouraged to seek immediate medical care provided by your health care provider, which may keep you from participating in the project.

Weeks 2 through 11 will be devoted to the education program whereby you will learn about diet, physical activity, and self-care management of diabetes. The following timeline and procedures are involved in this study:

**Week 1** (about 60-90 minutes)

- You will report to your local clinic between 7-9 am for a **fasting** blood draw.
- **Fasting** means no food or beverage 8 hrs before the blood draw (water is allowed).
- A technician will draw ~ 50 ml (about 4 tablespoons) of your blood from a blood vessel in your forearm.
- Height, weight, and blood pressure will be obtained.
- Waist size will be measured using either a plastic or steel measuring tape.
- A healthy diabetic snack will then be offered and you will complete 2 questionnaires.
- If needed, you will receive assistance from a translator to complete the questionnaires.

**Weeks 2 through 11** (about 60-90 minutes for each session)

- These sessions will be offered on Saturday at 10 am.
- An education program will be presented about how to improve your diet and physical activity, and how to practice diabetic self-care.
- During week 2 you will receive a pedometer (a device used to measure how far you walk each day) and be given instructions on its use.
- You will be encouraged to walk outside of class and keep a journal of steps taken each day.
- The journal will be checked at each class session and will provide a quick means of checking how much you are walking between sessions.

**Week 12** (about 60-90 minutes-we will repeat the assessment measures taken during week 1)

- You will report to your local clinic between 7-9 am for a **fasting** blood draw.
- **Fasting** means no food or beverage 8 hrs before the blood draw (water is allowed).
- A technician will draw ~ 50 ml (about 4 tablespoons) of your blood from a blood vessel in your forearm.
- Height, weight, and blood pressure will be obtained.
- Waist size will be measured using either a plastic or steel measuring tape.
- A healthy diabetic snack will then be offered and you will complete 2 questionnaires.
- If needed, you will receive assistance from a translator to complete the questionnaires.

You will be contacted sometime after the project is completed to attend a follow-up session so that you can be given the general results of the study and your laboratory results. If you are unable to attend, the results will be mailed to you. You are encouraged to share the results with your physician. Results pertaining specifically to you will not be given to any other individual, unless the results from your blood work are abnormally high and at which time your physician will be notified.

### **RISKS**

The risks or discomforts with this study are minimal. During the course of this study a total of ~100 ml of blood, which is about 8 tablespoonfuls, will be taken from a blood vessel in your arm. Each blood sample taken will only be ~50 ml. There are a few potential risks associated with blood draws. Among them are: temporary discomfort from where the needle is inserted into the arm, bruising around the site where the blood was taken from, and rarely infection. To minimize these risks you will be instructed to keep pressure on the site where the blood was drawn for 1 minute and keep a bandage over the area for at least 1 hour. Blood will be analyzed for glucose (sugar), insulin, HgbA1c, and lipids by a laboratory technician.

You may experience emotional discomfort when completing the questionnaires. To reduce this discomfort, you will be completing these questionnaires away from other individuals, with a translator present nearby to assist in any questions or concerns you may have. All questionnaires are confidential and will not be criticized.

### **BENEFITS**

The potential personal benefits that may occur as a result of your participation in this study are as follows:

- Possible improvement in your risk factors for diabetic complications.
- An accurate measurement of your average dietary nutrient intake.
- A general health assessment profile.
- Increased knowledge about diabetes and ways to improve your health.
- A precise measurement of your fasting glucose, insulin, HgbA1c, and lipid levels.
- An indirect measurement of your insulin sensitivity (which lets you know how well your cells are responding to insulin).
- A pedometer for your use after the study.

The researchers anticipate that society may benefit from this study by helping to reduce the incidence of diabetes and its economic burden, and improve the quality of life for all persons who have or are at risk for diabetes.

### **COSTS AND COMPENSATIONS**

You will receive no payment for being in this study. There are minimal costs (transportation) for participating in this research project. You will be given a pedometer, food at each class, as well as prizes and incentives such as gift certificates to local businesses in the community.

OSU IRB Approval Date: 01-24-05 Approval Expiration Date: 01-23-06
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**CONFIDENTIALITY**

Records of participation in this research project will be kept confidential to the extent permitted by law. However, federal government regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies involving human subjects) may inspect and copy records pertaining to this research. It is possible that these records could contain information that personally identifies you. In the event of any report or publication from this study, your identity will not be disclosed. Results will be reported in a summarized manner in such a way that you cannot be identified.

**VOLUNTARY PARTICIPATION**

Taking part in this research study is voluntary. You may choose not to take part at all. If you agree to participate in this study, you may stop participating at any time. You will not be dropped from the study if you miss a class. If your support person chooses to drop out of the study you will be able to recruit a second support person. Involvement in this study requires that you fill out questionnaires. You are free to skip any questions that you would prefer not to answer. If you decide not to take part, or if you stop participating at any time, your decision will not result in any penalty or loss of benefits to which you may otherwise be entitled. Any data collected from you prior to withdrawal may be included in the study results.

**QUESTIONS**

Questions are encouraged. If you have any questions about this research project, please contact:

Dr. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

OR

Bev White (541) 737-9190, [bwhite@meritel.net](mailto:bwhite@meritel.net)

OR

Joel Pelayo (Nuestra Comunidad Sana) (541) 386-4880, [joelp@nextdoorinc.org](mailto:joelp@nextdoorinc.org)

OR

Sandra Guerrero (La Clinica Del Carino) (541) 308-8378, [sguerrero@lcdcfn.org](mailto:sguerrero@lcdcfn.org)

If you have questions about your rights as a participant, please contact the Oregon State University Institutional Review Board (IRB) Human Protections Administrator, at (541) 737-3437 or by e-mail at [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu).

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date)

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**RESEARCHER STATEMENT**

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

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(Signature of Researcher)

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(Date)



**Nutrition and Food Management**  
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T 541-737-3561 | F 541-737-6914

## **DOCUMENTO DE INFORMACIÓN Y CONSENTIMIENTO** **(Participante con diabetes)**

**Título del proyecto:** Investigación de diabetes en la familia hispana

**Investigadores:** Melinda M. Manore, Ph.D., R.D. y Bev White R.D., M.S.  
Departamento de Nutrición y Administración de Alimentos  
de la Universidad del Estado de Oregón

**Personas de contacto del** Joel Pelayo (Nuestra Comunidad Sana)  
**Condado Hood River:** Sandra Guerrero (La Clínica del Cariño)

### **PROPÓSITO**

El propósito de este estudio de investigación es determinar si un programa de educación sobre la diabetes, el cual incluye a una persona de apoyo, puede ayudarle a controlar su diabetes. El programa de educación incluirá información sobre dieta, actividad física y el cuidado propio del diabético. Nuestra meta es que, siguiendo el programa de educación, usted mejore sus factores de riesgo de diabetes (por ejemplo, dieta y actividad física) y sus resultados de laboratorio (glucosa de la sangre, lo que significa azúcar en la sangre, e insulina). Si se tuviera éxito, este programa tiene el potencial de mejorar su salud en general y de ser implementado en otros condados de Oregón.

El propósito de este documento de consentimiento es darle la información que usted necesitará para decidir si va a participar o no en el estudio. Por favor léalo cuidadosamente. Usted puede hacer cualesquiera preguntas acerca de la investigación, qué es lo que se le pedirá que haga, los posibles riesgos y beneficios, sus derechos como voluntario, y cualquiera otra pregunta acerca de la investigación o de algo que no esté claro en este documento. Cuando todas sus preguntas hayan sido contestadas, usted puede decidir si quiere o no participar en este estudio. Este documento se llama "Documento de información y consentimiento". Se le entregará una copia para sus archivos.

Lo invitamos a participar en este estudio de investigación porque usted es descendiente de hispanos y padece de diabetes. Además, tiene por lo menos 19 años de edad. Se involucrará en este estudio de investigación un total de 20 hombres y mujeres hispanos con diabetes con edad mínima de 19 años.

### **PROCEDIMIENTOS**

Si usted está de acuerdo en participar, necesitará visitar la clínica local de salud en su condado cada sábado a las 10 am por 12 semanas, para asistir a un programa de educación. Cada sesión durará de 60 a 90 minutos. Este programa será impartido en español por un trabajador de la salud de la comunidad. La asistencia es de vital importancia ya que cada semana se discutirá un

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tópico nuevo. Se registrará su asistencia y la de la persona que lo apoya y lo ayuda. Este programa de educación comenzará en febrero de 2005.

En la primera y última sesiones se le presentarán dos cuestionarios para que los conteste (uno relacionado con la dieta y otro relacionado con su estado general de salud, actividad física e historia de su propio cuidado personal; por ejemplo, monitoreo de glucosa en la sangre, chequeo regular de sus pies por llagas, y con qué frecuencia visita al doctor). Además, se obtendrá de uno de sus brazos una muestra de sangre cuando no haya ingerido alimentos por varias horas. También mediremos su estatura, su peso, su presión arterial y su cintura. Su sangre será sometida a estudio para conocer los niveles de glucosa (azúcar), insulina, HgbA1c (un indicador del nivel de azúcar en la sangre), y lípidos (por ejemplo, colesterol). Usted será notificado de los resultados de laboratorio hasta el final del estudio, pero si los resultados son altamente anormales se le notificará inmediatamente y una copia de tales resultados se le enviará a su médico. En este punto, se le recomendará que busque el cuidado de su médico de cabecera, quien probablemente no le permitirá que continúe participando en el proyecto.

Las semanas de la 2ª hasta la 11ª estarán dedicadas al programa de educación donde usted puede aprender acerca de la dieta, actividad física, y su propio cuidado personal para el control de la diabetes. El horario y procedimientos siguientes están comprendidos en este estudio:

**1ª. Semana** (de 60 a 90 minutos)

- Se presentará en **ayunas** en su clínica local entre 7 y 9 a.m., para un examen de sangre.
- **Ayuno (ayunas)** significa no ingerir alimentos ni beber líquidos durante 8 horas antes del examen (beber agua está permitido).
- Un técnico extraerá ~ 50 ml. (como 4 cucharadas) de sangre de una vena de uno de sus antebrazos.
- Se le tomará su altura, peso y presión arterial.
- La cintura se le medirá con una cinta de medir plástica o de aluminio.
- Usted llenará dos cuestionarios y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar los cuestionarios.

**De la 2ª hasta la 11ª semana.** (De 60 a 90 minutos para cada clase)

- Estas clases serán ofrecidas los sábados a las 10 am..
- Se presentará un programa educativo acerca de cómo mejorar su dieta y actividad física, y cómo practicar el propio cuidado personal con relación a la diabetes.
- En la segunda clase usted recibirá un podómetro (aparato para medir cuánto camina cada día) y se le darán instrucciones para su uso.
- Se le recomendará que camine cuando no esté en clase y para que lleve un diario para anotar los pasos dados cada día..
- El diario será revisado en cada sesión de clase y proveerá una rápida información de cuánto está caminando entre clases.

**Semana 12ª.** (Durante 60 a 90 minutos repetiremos las medidas de evaluación tomadas en la 1ª la primera clase)

- Se presentará en **ayunas** en su clínica local entre 7 y 9 a.m., para un examen de sangre.



- **Ayuno (ayunas)** significa no ingerir alimentos ni beber líquidos durante 8 horas antes del examen (beber agua está permitido).
- Un técnico extraerá ~ 50 ml. (como 4 cucharadas) de su sangre de una vena de uno de sus antebrazos.
- Se le tomará su altura, peso y presión arterial.
- La cintura se le medirá con una cinta de medir plástica o de aluminio.
- Usted llenará dos cuestionarios y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar los cuestionarios.

Una vez que el proyecto esté completo, nos comunicaremos con usted para que asista a una sesión de seguimiento y será informado de los resultados generales del estudio y del laboratorio. En el caso de que usted no pudiera asistir, los resultados le serán enviados por correo. Le sugerimos que comparta los resultados con su médico. Los resultados específicamente pertinentes a usted no serán dados a ninguna otra persona. A menos que los resultados de sus análisis de sangre estén anormalmente altos, se le notificará a su médico inmediatamente.

### **RIESGOS**

Los riesgos o incomodidad con los procedimientos de este estudio son mínimos. Durante el curso de este estudio le será extraído de una vena de uno de sus antebrazos un total de ~100 ml de sangre, que son más o menos 8 cucharadas. Cada muestra de sangre tomada será solamente de ~50 ml. Hay muy pocos riesgos potenciales asociados con la extracción de sangre. Entre ellos están: incomodidad temporal en el lugar donde la aguja es insertada en el brazo, moretones alrededor del sitio donde la sangre fue extraída, y raramente una infección. Para minimizar los riesgos usted será instruido a fin de que haga presión por 1 minuto en el lugar de donde la sangre fue tomada y que se deje puesta una curita en ese lugar por lo menos una hora. La sangre será analizada por un técnico de laboratorio para investigar glucosa (azúcar), insulina, HgbA1c, y lípidos.

Posiblemente usted experimente alguna incomodidad emocional cuando esté llenando los cuestionarios. Para reducir esta incomodidad usted llenará los cuestionarios lejos de otras personas, con un traductor que estará cerca de usted para atenderlo en cualesquiera preguntas o inquietudes que usted tenga. Todos los cuestionarios son confidenciales y no serán criticados.

### **BENEFICIOS**

Los potenciales beneficios personales que pueden ocurrir como resultado de su participación en este estudio son los siguientes:

- Posible mejora en sus factores de riesgos por complicaciones diabéticas.
- Una medida segura del promedio de nutrientes que deberá tomar en su dieta.
- Una evaluación del perfil general de su salud.
- Mayor conocimiento acerca de la diabetes y formas de mejorar su salud.
- Una medida precisa de su glucosa en ayunas, insulina, HgbA1c, y niveles de lípidos.
- Una medida indirecta de su sensibilidad a la insulina (la cual le hará saber cómo están respondiendo sus células a la insulina).

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- Un podómetro para su uso después del estudio.

Los investigadores dan por anticipado que la sociedad podrá ser beneficiada con este estudio al ayudar a reducir la incidencia de diabetes y su costo económico, y a mejorar la calidad de vida de todas aquellas personas que tengan o estén en riesgo por la diabetes.

### **COSTOS Y COMPENSACIONES**

Usted no recibirá pago alguno por participar en este estudio. Hay costos mínimos (transporte) por participar en este proyecto de investigación. Se le entregará un podómetro, alimentos en cada clase, así como premios e incentivos, tales como certificados de regalo de comercios locales en la comunidad.

### **CONFIDENCIALIDAD**

Los registros de participación en este proyecto de investigación serán guardados en forma confidencial por el tiempo que permita la ley. Sin embargo, las agencias reguladoras del gobierno federal y la Junta Examinadora Institucional de la Universidad del Estado de Oregon (Oregon State University Institutional Review Board) - un comité que examina y aprueba los estudios de investigación que involucran tópicos humanos - pueden inspeccionar y copiar registros pertinentes a esta investigación. Es posible que estos registros pudieran contener información que lo identifique personalmente a usted. En el eventual caso de cualquier informe o publicación de este estudio, su identidad no será dada a conocer. Los resultados serán informados de manera resumida, de tal manera que usted no podría ser identificado.

### **PARTICIPACIÓN VOLUNTARIA**

Tomar parte en este estudio es una decisión voluntaria. Usted puede escoger no tomar parte. Aun si usted está de acuerdo en participar en este estudio, puede dejar de hacerlo en cualquier tiempo. Usted no será eliminado del estudio si pierde una clase. Si la persona que lo apoya escoge salirse del estudio, usted puede elegir una segunda persona para que sustituya a la anterior. El involucrarse en este estudio requiere que usted llene algunos cuestionarios. Siéntase en libertad de no contestar cualesquiera preguntas si prefiere no contestarlas. Si decide no tomar parte, o si prefiere no seguir participando en cualquier momento, su decisión no será motivo de penalidad alguna ni de pérdida de beneficios a los cuales usted pudiera tener derecho. Otros datos obtenidos sobre usted antes de su retiro del proyecto podrían ser incluidos en los resultados de este estudio.

### **PREGUNTAS**

Las preguntas son bien recibidas, por lo que le recomendamos que las haga si tiene algunas dudas. Si tiene preguntas acerca de este proyecto de investigación, por favor comuníquese con:

Dra. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

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Bev White (541) 737-9190, bwhite@meritel.net

O

Joel Pelayo (Nuestra Comunidad Sana) (541) 386-4880, joelp@nexdoorinc.org

O

Sandra Guerrero (La Clínica del Cariño) (541) 308-8378, sguerrero@cdcfdh.org

Si tiene preguntas acerca de sus derechos como participante, por favor comuníquese con el Administrador de las Protecciones Humanas (Human Protections Administrator) de la Junta Examinadora Institucional de la Univesidad de Oregon (Oregon State University Institutional Review Board (IRB) en el número telefónico (541) 737-3437 o por el correo electrónico IRB@oregonstate.edu

Su firma indica que este estudio de investigación le ha sido explicado, que sus preguntas han sido contestadas, y que está de acuerdo en participar en este estudio. Se le entregará copia de este formulario.

Nombre del participante (en letra de imprenta):

\_\_\_\_\_

\_\_\_\_\_  
(Firma del participante)

\_\_\_\_\_  
(Fecha)

#### **DECLARACIÓN DEL INVESTIGADOR**

He discutido con el participante los puntos antes mencionados o, donde era apropiado, con el representante legalmente autorizado del participante y, cuando fue necesario, usando los servicios de un traductor. En mi opinión, el participante entiende los riesgos, beneficios, y procedimientos involucrados con su participación en este estudio de investigación.

\_\_\_\_\_  
(Firma del Investigador)

\_\_\_\_\_  
(Fecha)

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## **INFORMED CONSENT DOCUMENT** **(Support participant)**

**Project Title:** **Hispanic Family Diabetes Project**

**Investigators:** **Melinda M. Manore, Ph.D., R.D. & Bev White R.D., M.S.**  
**Department of Nutrition and Food Management**  
**Oregon State University**

**Contact persons from Hood River County:** **Joel Pelayo (Nuestra Comunidad Sana)**  
**Sandra Guerrero (La Clinica Del Carino)**

### **PURPOSE**

The purpose of this research study is to determine whether a diabetes education program, where you are the support person, can help your partner with diabetes in managing their disease. Your role in this research study is to help your partner with diabetes make healthy lifestyle changes. The education program will include information on diet, physical activity, and diabetic self-care. Our goal is that the individual you are supporting that has diabetes will improve their diabetes risk factors (for example diet and physical activity) and their laboratory values (blood glucose, which means blood sugar, and insulin) following the education program. If successful, this program has the potential to improve the overall health of the diabetic individual you are supporting and to be implemented in other counties in Oregon.

The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study or not. Please read the form carefully. You may ask any questions about the research, what you will be asked to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all of your questions have been answered, you can decide if you want to be in this study or not. This process is called "informed consent". You will be given a copy of this form for your records.

We are inviting you to participate in this research study because you are the support person of a Hispanic individual that has diabetes. In addition, you are at least 19 years or older. A minimum of 20 male and female support persons, ages 19 years and older will be recruited. If you yourself have diabetes you will be asked to be part of the diabetic population for this study and an additional informed consent document will need to be filled out.

### **PROCEDURES**

If you agree to participate, you will need to visit the local health clinic in your county every Saturday at 10 am for 12 weeks, to attend an education program with your partner that has diabetes. Each session will last 60-90 minutes. This program will be taught in Spanish by a

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community health worker. Attendance is strongly encouraged since each week a new topic will be discussed. Attendance for both you and the individual with diabetes you are supporting will be recorded. This education program will begin in February of 2005.

The first and last sessions will involve answering a questionnaire that will ask you questions regarding your relationship with the individual who has diabetes that you are supporting. In all, you will answer 2 questionnaires (one each on the first and last sessions). Weeks 2 through 11 will be devoted to the education program whereby you will learn about diet, physical activity, and diabetic self-care management.

The following timeline and procedures are involved in this study:

**Week 1** (about 60-90 minutes)

- You will report to your local clinic between 7-9 am with your partner that has diabetes.
- A healthy diabetic snack will be offered and you will complete 1 questionnaire regarding your relationship with the individual who has diabetes that you are supporting.
- If needed, you will receive assistance from a translator to complete the questionnaire.

**Weeks 2 through 11** (about 60-90 minutes for each session)

- These sessions will be offered on Saturday at 10 am.
- An education program will be presented about how to improve the diet, physical activity, and self-care management of your partner who has diabetes.
- During week 2 you will receive a pedometer (a device used to measure how far you walk each day) and be given instructions on its use.
- You will be encouraged to walk outside of class with your partner that has diabetes and keep a journal of your steps taken each day.

**Week 12** (about 60-90 minutes)

- You will report to your local clinic between 7-9 am with your partner that has diabetes.
- A healthy diabetic snack will be offered and you will complete 1 questionnaire regarding your relationship with the individual who has diabetes that you are supporting.
- If needed, you will receive assistance from a translator to complete the questionnaire.

You will be contacted sometime after the project is completed to attend a follow-up session so that you can be given the results of the study. If you are unable to attend, the results will be mailed to you.

**RISKS**

The risks or discomforts with this study are minimal. You may experience emotional discomfort when completing the questionnaires. To reduce this discomfort, you will be completing these questionnaires away from other individuals, with a translator present nearby to assist in any

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questions or concerns you may have. All questionnaires are confidential and will not be criticized.

### **BENEFITS**

The potential personal benefits that may occur as a result of your participation in this study are as follows:

- Increased knowledge about diabetes and ways to improve the health of the individual with diabetes you are supporting.
- A pedometer for your use after the study.
- Improvement in the risk factors for diabetic complications of your partner with diabetes.

The researchers anticipate that society may benefit from this study by helping to reduce the incidence of diabetes and its economic burden, and improve the quality of life for all persons who have or are at risk for diabetes.

### **COSTS AND COMPENSATIONS**

You will receive no payment for being in this study. There are minimal costs (transportation) for participating in this research project. You will be given a pedometer, food at each class, as well as prizes and incentives such as gift certificates to local businesses in the community.

### **CONFIDENTIALITY**

Records of participation in this research project will be kept confidential to the extent permitted by law. However, federal government regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies involving human subjects) may inspect and copy records pertaining to this research. It is possible that these records could contain information that personally identifies you. In the event of any report or publication from this study, your identity will not be disclosed. Results will be reported in a summarized manner in such a way that you cannot be identified.

### **VOLUNTARY PARTICIPATION**

Taking part in this research study is voluntary. You may choose not to take part at all. If you agree to participate in this study, you may stop participating at any time. You will not be dropped from the study if you miss a class. If you choose to drop out of the study your partner with diabetes may recruit a second support person. Involvement in this study requires that you fill out questionnaires. You are free to skip any questions that you would prefer not to answer. If you decide not to take part, or if you stop participating at any time, your decision will not result in any penalty or loss of benefits to which you may otherwise be entitled. Any data collected from you prior to withdrawal may be included in the study results.

### **QUESTIONS**

Questions are encouraged. If you have any questions about this research project, please contact:

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Dr. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

OR

Bev White (541) 737-9190, [bwhite@meritel.net](mailto:bwhite@meritel.net)

OR

Joel Pelayo (Nuestra Comunidad Sana) (541) 386-4880, [joelp@nextdoorinc.org](mailto:joelp@nextdoorinc.org)

OR

Sandra Guerrero (La Clinica Del Carino) (541) 308-8378, [sguerrero@lcdcfc.org](mailto:sguerrero@lcdcfc.org)

If you have questions about your rights as a participant, please contact the Oregon State University Institutional Review Board (IRB) Human Protections Administrator, at (541) 737-3437 or by e-mail at [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu).

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date)

#### **RESEARCHER STATEMENT**

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

\_\_\_\_\_  
(Signature of Researcher)

\_\_\_\_\_  
(Date)

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## **DOCUMENTO DE INFORMACIÓN Y CONSENTIMIENTO** **(Participante de apoyo)**

Título del proyecto: **Investigación de diabetes en la familia hispana**

Investigadores: **Melinda M. Manore, Ph.D., R.D. & Bev White R.D., M.S.**  
**Departamento de Nutrición y Administración de Alimentos**  
**de la Universidad del Estado de Oregón**

Personas de contacto del Condado Hood River: **Joel Pelayo (Nuestra Comunidad Sana)**  
**Sandra Guerrero (La Clínica del Cariño)**

### **PROPÓSITO**

El propósito de este estudio de investigación es determinar si un programa de educación sobre la diabetes, en el que usted participa como persona de apoyo, puede ayudar a su compañero(a) con diabetes a controlar su enfermedad. Su rol en este estudio de investigación es ayudar a su compañero(a) con diabetes a hacer cambios saludables en su estilo de vida. El programa de educación incluirá información sobre dieta, actividad física, y cuidado personal del propio diabético. Nuestra meta es que la persona a quien usted está ayudando y que tiene diabetes pueda mejorar sus factores de riesgos de diabetes (por ejemplo, dieta y actividad física) y sus evaluaciones de laboratorio (glucosa en la sangre, lo cual significa azúcar en la sangre, e insulina), siguiendo el programa de educación. Si se tuviera éxito, este programa tiene el potencial de mejorar la salud en general de la persona diabética que usted está ayudando y de ser implementado en otros condados de Oregón.

El propósito de este documento de consentimiento es darle la información que usted necesitará para ayudarlo a decidir si participará o no en el estudio. Por favor léalo cuidadosamente. Usted podrá hacer cualesquiera preguntas acerca de la investigación, qué es lo que se le pedirá que haga, los posibles riesgos y beneficios, sus derechos como voluntario, y cualquiera otra pregunta acerca de la investigación o de algo que no esté claro en este formulario. Cuando todas sus preguntas hayan sido contestadas, usted puede decidir si quiere o no participar en este estudio. Este documento se llama "Documento de información y consentimiento". Se le entregará una copia para sus archivos.

Lo invitamos a participar en este estudio de investigación porque usted es la persona de apoyo de una persona hispana que padece diabetes. Además, usted tiene por lo menos 19 años de edad. Se reclutará un mínimo de 20 hombres y mujeres que están sirviendo de apoyo, con edad mínima de 19 años. Si usted mismo padece de diabetes, se le pedirá que sea parte de la población diabética para este estudio en calidad de paciente, para lo cual será necesario llenar un documento de información y consentimiento adicional.

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## **PROCEDIMIENTOS**

Si usted está de acuerdo en participar, necesitará visitar la clínica local de salud en su condado cada sábado a las 10 a.m. por 12 semanas para asistir a un programa de educación con su compañero(a) que tiene diabetes. Cada sesión durará de 60 a 90 minutos. Este programa será impartido en español por un trabajador de la salud de la comunidad. La asistencia es de vital importancia ya que cada semana se discutirá un tópico nuevo. Se registrará su asistencia y la de la persona con diabetes a la que está apoyando. Este programa de educación comenzará en febrero de 2005.

En la primera y última clases se le presentarán dos cuestionarios en los que se le harán preguntas referentes a su relación con la persona que tiene diabetes a la que usted está apoyando. En total, usted contestará dos cuestionarios (uno en la primera clase y otro en la última). Las semanas de la 2a., hasta la 11a., estarán dedicadas al programa de educación en donde usted podrá aprender acerca de la dieta, actividad física y el cuidado personal para el control del diabético.

El horario y los procedimientos que siguen están comprendidos en este estudio:

### **1a. Semana** (de 60 a 90 minutos)

- Se presentará en su clínica local entre 7 y 9 a.m., con su compañero(a) que tiene diabetes.
- Usted contestará referente a su relación con la persona que tiene diabetes y que usted está apoyando y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar el cuestionario.

### **De la 2a. semana hasta la 11a.** (De 60 a 90 minutos para cada clase)

- Estas clases serán ofrecidas los sábados a las 10 am.
- Se presentará un programa educativo acerca de cómo mejorar la dieta, actividad física, y propio cuidado personal de su compañero(a) con diabetes.
- En la segunda clase usted recibirá un podómetro (aparato para medir cuánto camina cada día) y se le darán instrucciones para su uso.
- Se le recomendará que cuando no esté en clase camine con su compañero(a) que padece de diabetes, y para que lleve un diario para anotar sus pasos dados cada día.

### **Semana 12a.** (De 60 a 90 minutos)

- Usted y su compañero(a) con diabetes se presentarán a su clínica local entre 7 y 9 a.m.
- Usted llenará un cuestionario referente a su relación con la persona con diabetes a quien está ayudando y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar el cuestionario.

Una vez que el proyecto esté completo, nos comunicaremos con usted para que asista a una sesión de seguimiento y será informado de los resultados del estudio. Si no le fuere posible asistir, los resultados le serán enviados por correo.

### **RIESGOS**

Los riesgos o incomodidades con los procedimientos de este estudio son mínimos. Posiblemente usted experimente alguna incomodidad emocional cuando esté llenando los cuestionarios. Para reducir esta incomodidad, usted llenará los cuestionarios lejos de otras personas, con un traductor que estará cerca de usted para atenderlo en cualesquiera preguntas o inquietudes que usted tenga. Todos los cuestionarios son confidenciales y no serán criticados.

### **BENEFICIOS**

Los potenciales beneficios personales que pueden ocurrir como resultado de su participación en este estudio son los siguientes:

- Mayor conocimiento acerca de la diabetes y formas de mejorar la salud de la persona con diabetes que está apoyando.
- Un podómetro para su uso después del estudio.
- Mejoras en los factores de riesgo por complicaciones por diabetes de su compañero(a) con diabetes.

Los investigadores dan por anticipado que la sociedad podrá ser beneficiada con este estudio al ayudar a reducir la incidencia de diabetes y su costo económico, y a mejorar la calidad de vida de todas aquellas personas que tengan o estén en riesgo por la diabetes.

### **COSTOS Y COMPENSACIONES**

Usted no recibirá pago alguno por participar en este estudio. Hay costos mínimos (transporte) por participar en este proyecto de investigación. Se le entregará un podómetro, alimentos en cada clase, así como premios e incentivos, tales como certificados de regalo de comercios locales en la comunidad.

### **CONFIDENCIALIDAD**

Los registros de participación en este proyecto de investigación serán guardados en forma confidencial por el tiempo que permita la ley. Sin embargo, las agencias reguladoras del gobierno federal y la Junta Examinadora Institucional de la Universidad del Estado de Oregón (Oregon State University Institutional Review Board) - un comité que examina y aprueba los estudios de investigación que involucran tópicos humanos - pueden inspeccionar y copiar registros pertinentes a esta investigación. Es posible que estos registros pudieran contener información que lo identifique personalmente a usted. En el eventual caso de cualquier informe o publicación de este estudio, su identidad no será dada a conocer. Los resultados serán informados de manera resumida, de tal manera que usted no podría ser identificado.

### **PARTICIPACIÓN VOLUNTARIA**

Tomar parte en este estudio es una decisión voluntaria. Usted puede escoger no tomar parte. Aun si usted está de acuerdo en participar en este estudio, puede dejar de hacerlo en cualquier

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tiempo. Si usted decide salirse del estudio, su compañero(a) con diabetes puede reclutar a otra persona para que lo sustituya a usted. El involucrarse en este estudio requiere que usted llene algunos cuestionarios. Siéntase en libertad de no contestar cualesquiera preguntas si prefiere no contestarlas. Si decide no tomar parte, o si prefiere no seguir participando en cualquier momento, su decisión no será motivo de multa alguna ni de pérdida de beneficios a los cuales usted pudiera tener derecho. Otros datos obtenidos sobre usted antes de su retiro del proyecto podrían ser incluidos en los resultados de este estudio.

### **PREGUNTAS**

Las preguntas son bien recibidas, por lo que le recomendamos que las haga si tiene algunas dudas. Si tiene preguntas acerca de este proyecto de investigación, por favor comuníquese con:

Dra. Melinda Manore (541) 737-8701, melinda.manore@oregonstate.edu

O

Bev White (541) 737-9190, bwhite@meritel.net

O

Joel Pelayo (Nuestra Comunidad Sana) (541) 386-4880  
joelp@nextdoorinc.org

O

Sandra Guerrero (La Clínica del Cariño) (541) 308-8378 sguerrero@lclcfh.org

Si tiene preguntas acerca de sus derechos como participante de apoyo, por favor comuníquese con el Administrador de las Protecciones Humanas (Human Protections Administrator) de la Junta Examinadora Institucional de la Universidad de Oregon (Oregon State University Institutional Review Board (IRB) en el número telefónico (541) 737-3437 o por el correo electrónico IRB@oregonstate.edu

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Su firma indica que este estudio de investigación le ha sido explicado, que sus preguntas han sido contestadas, y que está de acuerdo en participar en este estudio. Se le entregará copia de este formulario.

Nombre del participante de apoyo (en letra de imprenta):

---

(Firma del participante de apoyo)	fecha
-----------------------------------	-------

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**DECLARACIÓN DEL INVESTIGADOR**

He discutido con el participante de apoyo los puntos antes mencionados o, donde era apropiado, con su representante legalmente autorizado y, cuando fue necesario, usando los servicios de un traductor. En mi opinión, el participante entiende los riesgos, beneficios, y procedimientos involucrados con su participación en este estudio de investigación.

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(Firma del Investigador)

---

(Fecha)

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## Appendix 9

Informed Consent Documents - for both the participant with diabetes and support participant in Multnomah County (English and Spanish)



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## INFORMED CONSENT DOCUMENT (Participant with diabetes)

Project Title: **Hispanic Family Diabetes Project**

Investigators: **Melinda M. Manore, Ph.D., R.D. & Bev White R.D., M.S.**  
**Department of Nutrition and Food Management**  
**Oregon State University**

Contact person from  
Multnomah County: **Ruby Ibarra**

### PURPOSE

The purpose of this research study is to determine whether a diabetes education program, which includes a support person, can help in managing your diabetes. The education program will include information on diet, physical activity, and diabetic self-care. Our goal is that you will improve your diabetes risk factors (for example diet and physical activity) and your laboratory values (blood glucose, which means blood sugar, and insulin) following the education program. If successful, this program has the potential to improve your overall health and to be implemented in other counties in Oregon.

The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study or not. Please read the form carefully. You may ask any questions about the research, what you will be asked to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all of your questions have been answered, you can decide if you want to be in this study or not. This process is called "informed consent". You will be given a copy of this form for your records.

We are inviting you to participate in this research study because you are of Hispanic descent and have diabetes. In addition, you are at least 19 years or older. Male and female diabetic Hispanics, ages 19 years and older will be recruited.

### PROCEDURES

If you agree to participate, you will need to visit the local health clinic in your county one time per week (\_\_\_\_\_ day/time) for 12 weeks to attend an education program. Each session will last ~120 minutes. This program will be taught in Spanish by a community health worker. Attendance is strongly encouraged since each week a new topic will be discussed. Attendance for both you and your social support person will be recorded. This education program will begin in February 2005.

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The first and last sessions will involve answering 2 questionnaires (one related to diet and one related to general health status, physical activity, and self-care history; for example blood glucose monitoring, checking your feet regularly for sores, and how often you visit a doctor). In addition 1 blood sample will be obtained from your arm at a time when you have not eaten for several hours. We will also measure your height, weight, blood pressure, and waist size. Your blood will be studied for levels of glucose (sugar), insulin, HgbA1c (a chemical marker for diabetes), and lipids (for example, cholesterol). You will not be notified of your laboratory results until the end of the study unless the results are highly abnormal. If the results are highly abnormal, you will be notified and a copy of the results will be sent to your physician. At this point, you will be encouraged to seek immediate medical care provided by your health care provider, which may keep you from participating in the project.

Weeks 2 through 11 will be devoted to the education program whereby you will learn about diet, physical activity, and self-care management of diabetes. The following timeline and procedures are involved in this study:

**Week 1** (about 120 minutes)

- You will report to your local clinic for a **fasting** blood draw.
- **Fasting** means no food or beverage 8 hrs before the blood draw (water is allowed).
- A technician will draw ~ 50 ml (about 4 tablespoons) of your blood from a blood vessel in your forearm.
- Height, weight, and blood pressure will be obtained.
- Waist size will be measured using either a plastic or steel measuring tape.
- A healthy diabetic snack will then be offered and you will complete 2 questionnaires.
- If needed, you will receive assistance from a translator to complete the questionnaires.

**Weeks 2 through 11** (about 120 minutes for each session)

- These sessions will be offered 1 time per week on the same day and at the same time.
- An education program will be presented about how to improve your diet and physical activity, and how to practice diabetic self-care.
- During week 2 you will receive a pedometer (a device used to measure how far you walk each day) and be given instructions on its use.
- You will be encouraged to walk outside of class and keep a journal of steps taken each day.
- The journal will be checked at each class session and will provide a quick means of checking how much you are walking between sessions.

**Week 12** (about 120 minutes-we will repeat the assessment measures taken during week 1)

- You will report to your local clinic for a **fasting** blood draw.
- **Fasting** means no food or beverage 8 hrs before the blood draw (water is allowed).
- A technician will draw ~ 50 ml (about 4 tablespoons) of your blood from a blood vessel in your forearm.
- Height, weight, and blood pressure will be obtained.
- Waist size will be measured using either a plastic or steel measuring tape.
- A healthy diabetic snack will then be offered and you will complete 2 questionnaires.
- If needed, you will receive assistance from a translator to complete the questionnaires.

You will be contacted sometime after the project is completed to attend a follow-up session so that you can be given the general results of the study and your laboratory results. If you are unable to attend, the results will be mailed to you. You are encouraged to share the results with your physician. Results pertaining specifically to you will not be given to any other individual, unless the results from your blood work are abnormally high and at which time your physician will be notified.

### **RISKS**

The risks or discomforts with this study are minimal. During the course of this study a total of ~100 ml of blood, which is about 8 tablespoonfuls, will be taken from a blood vessel in your arm. Each blood sample taken will only be ~50 ml. There are a few potential risks associated with blood draws. Among them are: temporary discomfort from where the needle is inserted into the arm, bruising around the site where the blood was taken from, and rarely infection. To minimize these risks you will be instructed to keep pressure on the site where the blood was drawn for 1 minute and keep a bandage over the area for at least 1 hour. Blood will be analyzed for glucose (sugar), insulin, HgbA1c, and lipids by a laboratory technician.

You may experience emotional discomfort when completing the questionnaires. To reduce this discomfort, you will be completing these questionnaires away from other individuals, with a translator present nearby to assist in any questions or concerns you may have. All questionnaires are confidential and will not be criticized.

### **BENEFITS**

The potential personal benefits that may occur as a result of your participation in this study are as follows:

- Possible improvement in your risk factors for diabetic complications.
- An accurate measurement of your average dietary nutrient intake.
- A general health assessment profile.
- Increased knowledge about diabetes and ways to improve your health.
- A precise measurement of your fasting glucose, insulin, HgbA1c, and lipid levels.
- An indirect measurement of your insulin sensitivity (which lets you know how well your cells are responding to insulin).
- A pedometer for your use after the study.

The researchers anticipate that society may benefit from this study by helping to reduce the incidence of diabetes and its economic burden, and improve the quality of life for all persons who have or are at risk for diabetes.

### **COSTS AND COMPENSATIONS**

You will receive no payment for being in this study. There are minimal costs (transportation) for participating in this research project. You will be given a pedometer, snacks at each class, as well as prizes and incentives such as gift certificates to local businesses in the community. In addition, there will be day care available if you have young children that need to be watched while you are attending class.

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**CONFIDENTIALITY**

Records of participation in this research project will be kept confidential to the extent permitted by law. However, federal government regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies involving human subjects) may inspect and copy records pertaining to this research. It is possible that these records could contain information that personally identifies you. In the event of any report or publication from this study, your identity will not be disclosed. Results will be reported in a summarized manner in such a way that you cannot be identified.

**VOLUNTARY PARTICIPATION**

Taking part in this research study is voluntary. You may choose not to take part at all. If you agree to participate in this study, you may stop participating at any time. You will not be dropped from the study if you miss a class. If your support person chooses to drop out of the study you will be able to recruit a second support person. Involvement in this study requires that you fill out questionnaires. You are free to skip any questions that you would prefer not to answer. If you decide not to take part, or if you stop participating at any time, your decision will not result in any penalty or loss of benefits to which you may otherwise be entitled. Any data collected from you prior to withdrawal may be included in the study results.

**QUESTIONS**

Questions are encouraged. If you have any questions about this research project, please contact:

Dr. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

OR

Bev White (541) 737-9190, [bwhite@meritel.net](mailto:bwhite@meritel.net)

OR

Ruby Ibarra (503) 988-3663 x 83991, [rubilia.a.ibarra@co.multnomah.or.us](mailto:rubilia.a.ibarra@co.multnomah.or.us)

If you have questions about your rights as a participant, please contact the Oregon State University Institutional Review Board (IRB) Human Protections Administrator, at (541) 737-3437 or by e-mail at [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu).

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date)

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**RESEARCHER STATEMENT**

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

Researcher's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Researcher)

\_\_\_\_\_  
(Date)

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**Nutrition and Food Management**  
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## **DOCUMENTO DE INFORMACIÓN Y CONSENTIMIENTO** **(Participante con diabetes)**

Título del proyecto: **Investigación de diabetes en la familia hispana**

Investigadores: **Melinda M. Manore, Ph.D., R.D. y Bev White R.D., M.S.**  
**Departamento de Nutrición y Administración de Alimentos**  
**de la Universidad del Estado de Oregon**

Persona de contacto del  
Condado Multnomah: **Ruby Ibarra**

### **PROPÓSITO**

El propósito de este estudio de investigación es determinar si un programa de educación sobre la diabetes, el cual incluye a una persona de apoyo, puede ayudarle a controlar su diabetes. El programa de educación incluirá información sobre dieta, actividad física y el cuidado propio del diabético. Nuestra meta es que, siguiendo el programa de educación, usted mejore sus factores de riesgo de diabetes (por ejemplo, dieta y actividad física) y sus resultados de laboratorio (glucosa de la sangre, lo que significa azúcar en la sangre, e insulina). Si se tuviera éxito, este programa tiene el potencial de mejorar su salud en general y de ser implementado en otros condados de Oregon.

El propósito de este documento de consentimiento es darle la información que usted necesitará para decidir si va a participar o no en el estudio. Por favor léalo cuidadosamente. Usted puede hacer cualesquiera preguntas acerca de la investigación, qué es lo que se le pedirá que haga, los posibles riesgos y beneficios, sus derechos como voluntario, y cualquiera otra pregunta acerca de la investigación o de algo que no esté claro en este documento. Cuando todas sus preguntas hayan sido contestadas, usted puede decidir si quiere o no participar en este estudio. Este documento se llama "Documento de información y consentimiento". Se le entregará una copia para sus archivos.

Lo invitamos a participar en este estudio de investigación porque usted es descendiente de hispanos y padece de diabetes. Además, tiene por lo menos 19 años de edad. Se involucrará en este estudio de investigación hombres y mujeres hispanos con diabetes con edad mínima de 19 años.

### **PROCEDIMIENTOS**

Si usted está de acuerdo en participar, necesitará visitar la clínica local de salud en su condado una vez por semana (\_\_\_\_\_ día/hora) por 12 semanas para asistir a un programa de educación. Cada sesión durará ~120 minutos. Este programa será impartido en español por un trabajador de la salud de la comunidad. La asistencia es de vital importancia ya que cada semana

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se discutirá un tópico nuevo. Se registrará su asistencia y la de la persona que lo apoya y lo ayuda. Este programa de educación comenzará en febrero de 2005.

En la primera y última sesiones se le presentarán dos cuestionarios para que los conteste (uno relacionado con la dieta y otro relacionado con su estado general de salud, actividad física e historia de su propio cuidado personal; por ejemplo, monitoreo de glucosa en la sangre, chequeo regular de sus pies por llagas, y con qué frecuencia visita al doctor). Además, se obtendrá de uno de sus brazos una muestra de sangre cuando no haya ingerido alimentos por varias horas. También mediremos su estatura, su peso, su presión arterial y su cintura. Su sangre será sometida a estudio para conocer los niveles de glucosa (azúcar), insulina, HgbA1c (un indicador del nivel de azúcar en la sangre), y lípidos (por ejemplo, colesterol). Usted será notificado de los resultados de laboratorio hasta el final del estudio, pero si los resultados son altamente anormales se le notificará inmediatamente y una copia de tales resultados se le enviará a su médico. En este punto, se le recomendará que busque el cuidado de su médico de cabecera, quien probablemente no le permitirá que continúe participando en el proyecto.

Las semanas de la 2ª hasta la 11ª estarán dedicadas al programa de educación donde usted puede aprender acerca de la dieta, actividad física, y su propio cuidado personal para el control de la diabetes. El horario y procedimientos siguientes están comprendidos en este estudio:

**1ª. Semana** (de 120 minutos)

- Se presentará en **ayunas** en su clínica local, para un examen de sangre.
- **Ayuno (ayunas)** significa no ingerir alimentos ni beber líquidos durante 8 horas antes del examen (beber agua está permitido).
- Un técnico extraerá ~ 50 ml. (como 4 cucharadas) de sangre de una vena de uno de sus antebrazos.
- Se le tomará su altura, peso y presión arterial.
- La cintura se le medirá con una cinta de medir plástica o de aluminio.
- Usted llenará dos cuestionarios y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar los cuestionarios.

**De la 2ª hasta la 11ª semana.** (De 120 minutos para cada clase)

- Estas clases serán ofrecidas una vez por semana el mismo día de la semana y a la misma hora.
- Se presentará un programa educativo acerca de cómo mejorar su dieta y actividad física, y cómo practicar el propio cuidado personal con relación a la diabetes.
- En la segunda clase usted recibirá un podómetro (aparato para medir cuánto camina cada día) y se le darán instrucciones para su uso.
- Se le recomendará que camine cuando no esté en clase y para que lleve un diario para anotar los pasos dados cada día.
- El diario será revisado en cada sesión de clase y proveerá una rápida información de cuánto está caminando entre clases.

**Semana 12ª.** (Durante 120 minutos repetiremos las medidas de evaluación tomadas en la primera clase)

- Se presentará en **ayunas** en su clínica local, para un examen de sangre.
- **Ayuno (ayunas)** significa no ingerir alimentos ni beber líquidos durante 8 horas antes del examen (beber agua está permitido).
- Un técnico extraerá ~ 50 ml. (como 4 cucharadas) de su sangre de una vena de uno de sus antebrazos.
- Se le tomará su altura, peso y presión arterial.
- La cintura se le medirá con una cinta de medir plástica o de aluminio.
- Usted llenará dos cuestionarios y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar los cuestionarios.

Una vez que el proyecto esté completo, nos comunicaremos con usted para que asista a una sesión de seguimiento y será informado de los resultados generales del estudio y del laboratorio. En el caso de que usted no pudiera asistir, los resultados le serán enviados por correo. Le sugerimos que comparta los resultados con su médico. Los resultados específicamente pertinentes a usted no serán dados a ninguna otra persona. A menos que los resultados de su análisis de sangre estén anormalmente altos, se le notificará a su médico inmediatamente.

### **RIESGOS**

Los riesgos o incomodidad con los procedimientos de este estudio son mínimos. Durante el curso de este estudio le será extraído de una vena de uno de sus antebrazos un total de ~100 ml de sangre, que son más o menos 8 cucharadas. Cada muestra de sangre tomada será solamente de ~50 ml. Hay muy pocos riesgos potenciales asociados con la extracción de sangre. Entre ellos están: incomodidad temporal en el lugar donde la aguja es insertada en el brazo, moretones alrededor del sitio donde la sangre fue extraída, y raramente una infección. Para minimizar los riesgos usted será instruido a fin de que haga presión por 1 minuto en el lugar de donde la sangre fue tomada y que se deje puesta una curita en ese lugar por lo menos una hora. La sangre será analizada por un técnico de laboratorio para investigar glucosa (azúcar), insulina, HgbA1c, y lípidos.

Posiblemente usted experimente alguna incomodidad emocional cuando esté llenando los cuestionarios. Para reducir esta incomodidad usted llenará los cuestionarios lejos de otras personas, con un traductor que estará cerca de usted para atenderlo en cualesquiera preguntas o inquietudes que usted tenga. Todos los cuestionarios son confidenciales y no serán criticados.

### **BENEFICIOS**

Los potenciales beneficios personales que pueden ocurrir como resultado de su participación en este estudio son los siguientes:

- Posible mejora en sus factores de riesgos por complicaciones diabéticas.
- Una medida segura del promedio de nutrientes que deberá tomar en su dieta.
- Una evaluación del perfil general de su salud.
- Mayor conocimiento acerca de la diabetes y formas de mejorar su salud.
- Una medida precisa de su glucosa en ayunas, insulina, HgbA1c, y niveles de lípidos.

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- Una medida indirecta de su sensibilidad a la insulina (la cual le hará saber cómo están respondiendo sus células a la insulina).
- Un podómetro para su uso después del estudio.

Los investigadores dan por anticipado que la sociedad podrá ser beneficiada con este estudio al ayudar a reducir la incidencia de diabetes y su costo económico, y a mejorar la calidad de vida de todas aquellas personas que tengan o estén en riesgo por la diabetes.

### **COSTOS Y COMPENSACIONES**

Usted no recibirá pago alguno por participar en este estudio. Hay costos mínimos (transporte) por participar en este proyecto de investigación. Se le entregará un podómetro, bocadillos en cada clase, así como premios e incentivos, tales como certificados de regalo de comercios locales en la comunidad. Además, habrá cuidado de niños disponible si tiene niños que necesiten ser atendidos mientras usted está asistiendo a clase.

### **CONFIDENCIALIDAD**

Los registros de participación en este proyecto de investigación serán guardados en forma confidencial por el tiempo que permita la ley. Sin embargo, las agencias reguladoras del gobierno federal y la Junta Examinadora Institucional de la Universidad del Estado de Oregon (Oregon State University Institutional Review Board) - un comité que examina y aprueba los estudios de investigación que involucran tópicos humanos - pueden inspeccionar y copiar registros pertinentes a esta investigación. Es posible que estos registros pudieran contener información que lo identifique personalmente a usted. En el eventual caso de cualquier informe o publicación de este estudio, su identidad no será dada a conocer. Los resultados serán informados de manera resumida, de tal manera que usted no podría ser identificado.

### **PARTICIPACIÓN VOLUNTARIA**

Tomar parte en este estudio es una decisión voluntaria. Usted puede escoger no tomar parte. Aun si usted está de acuerdo en participar en este estudio, puede dejar de hacerlo en cualquier tiempo. Usted no será eliminado del estudio si pierde una clase. Si la persona que lo apoya escoge salirse del estudio, usted puede elegir una segunda persona para que sustituya a la anterior. El involucrarse en este estudio requiere que usted llene algunos cuestionarios. Siéntase en libertad de no contestar cualesquiera preguntas si prefiere no contestarlas. Si decide no tomar parte, o si prefiere no seguir participando en cualquier momento, su decisión no será motivo de penalidad alguna ni de pérdida de beneficios a los cuales usted pudiera tener derecho. Otros datos obtenidos sobre usted antes de su retiro del proyecto podrían ser incluidos en los resultados de este estudio.

### **PREGUNTAS**

Las preguntas son bien recibidas, por lo que le recomendamos que las haga si tiene algunas dudas. Si tiene preguntas acerca de este proyecto de investigación, por favor comuníquese con:

Dra. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

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O

Bev White (541) 737-9190, bwhite@meritel.net

O

Ruby Ibarra (503) 988-3663 x 83991, rubilia.a.ibarra@co.multnomah.or.us

Si tiene preguntas acerca de sus derechos como participante, por favor comuníquese con el Administrador de las Protecciones Humanas (Human Protections Administrator) de la Junta Examinadora Institucional de la Univesidad de Oregon (Oregon State University Institutional Review Board (IRB) en el número telefónico (541) 737-3437 o por el correo electrónico IRB@oregonstate.edu.

Su firma indica que este estudio de investigación le ha sido explicado, que sus preguntas han sido contestadas, y que está de acuerdo en participar en este estudio. Se le entregará copia de este formulario.

Nombre del participante (en letra de imprenta):

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(Firma del participante)

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(Fecha)

### **DECLARACIÓN DEL INVESTIGADOR**

He discutido con el participante los puntos antes mencionados o, donde era apropiado, con el representante legalmente autorizado del participante y, cuando fue necesario, usando los servicios de un traductor. En mi opinión, el participante entiende los riesgos, beneficios, y procedimientos involucrados con su participación en este estudio de investigación.

Nombre del Investigador (en letra de imprenta):

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(Firma del Investigador)

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(Fecha)

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**Nutrition and Food Management**  
 Oregon State University, 108 Milam Hall, Corvallis, Oregon 97331-5103  
 T 541-737-3561 | F 541-737-6914

## **INFORMED CONSENT DOCUMENT** **(Support participant)**

**Project Title:** **Hispanic Family Diabetes Project**

**Investigators:** **Melinda M. Manore, Ph.D., R.D. & Bev White R.D., M.S.**  
**Department of Nutrition and Food Management**  
**Oregon State University**

**Contact person from**  
**Multnomah County:** **Ruby Ibarra**

### **PURPOSE**

The purpose of this research study is to determine whether a diabetes education program, where you are the support person, can help your partner with diabetes in managing their disease. Your role in this research study is to help your partner with diabetes make healthy lifestyle changes. The education program will include information on diet, physical activity, and diabetic self-care. Our goal is that the individual you are supporting that has diabetes will improve their diabetes risk factors (for example diet and physical activity) and their laboratory values (blood glucose, which means blood sugar, and insulin) following the education program. If successful, this program has the potential to improve the overall health of the diabetic individual you are supporting and to be implemented in other counties in Oregon.

The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study or not. Please read the form carefully. You may ask any questions about the research, what you will be asked to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all of your questions have been answered, you can decide if you want to be in this study or not. This process is called "informed consent". You will be given a copy of this form for your records.

We are inviting you to participate in this research study because you are the support person of a Hispanic individual that has diabetes. In addition, you are at least 19 years or older. Male and female support persons, ages 19 years and older will be recruited. If you yourself have diabetes you will be asked to be part of the diabetic population for this study and an additional informed consent document will need to be filled out.

### **PROCEDURES**

If you agree to participate, you will need to visit the local health clinic in your county one time per week, ( \_\_\_\_\_ day/ time), for 12 weeks to attend an education program with your

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partner that has diabetes. Each session will last ~120 minutes. This program will be taught in Spanish by a community health worker. Attendance is strongly encouraged since each week a new topic will be discussed. Attendance for both you and the individual you are supporting that has diabetes will be recorded. This education program will begin in February of 2005.

The first and last sessions will involve answering a questionnaire that will ask you questions regarding your relationship with the individual who has diabetes that you are supporting. In all, you will answer 2 questionnaires (one each on the first and last sessions). Weeks 2 through 11 will be devoted to the education program whereby you will learn about diet, physical activity, and diabetic self-care management.

The following timeline and procedures are involved in this study:

**Week 1** (about 120 minutes)

- You will report to your local clinic with your partner that has diabetes.
- A healthy diabetic snack will be offered and you will complete 1 questionnaire regarding your relationship with the individual who has diabetes that you are supporting.
- If needed, you will receive assistance from a translator to complete the questionnaire.

**Weeks 2 through 11** (about 120 minutes for each session)

- These sessions will be offered 1 time per week on the same day and at the same time.
- An education program will be presented about how to improve the diet, physical activity, and self-care management of your partner who has diabetes.
- During week 2 you will receive a pedometer (a device used to measure how far you walk each day) and be given instructions on its use.
- You will be encouraged to walk outside of class with your partner that has diabetes and keep a journal of your steps taken each day.

**Week 12** (about 120 minutes)

- You will report to your local clinic with your partner that has diabetes.
- A healthy diabetic snack will be offered and you will complete 1 questionnaire regarding your relationship with the individual who has diabetes that you are supporting.
- If needed, you will receive assistance from a translator to complete the questionnaire.

You will be contacted sometime after the project is completed to attend a follow-up session so that you can be given the results of the study. If you are unable to attend, the results will be mailed to you.

**RISKS**

The risks or discomforts with this study are minimal. You may experience emotional discomfort when completing the questionnaires. To reduce this discomfort, you will be completing these questionnaires away from other individuals, with a translator present nearby to assist in any

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questions or concerns you may have. All questionnaires are confidential and will not be criticized.

### **BENEFITS**

The potential personal benefits that may occur as a result of your participation in this study are as follows:

- Increased knowledge about diabetes and ways to improve the health of the individual with diabetes you are supporting.
- A pedometer for your use after the study.
- Improvement in the risk factors for diabetic complications of your partner with diabetes.

The researchers anticipate that society may benefit from this study by helping to reduce the incidence of diabetes and its economic burden, and improve the quality of life for all persons who have or are at risk for diabetes.

### **COSTS AND COMPENSATIONS**

You will receive no payment for being in this study. There are minimal costs (transportation) for participating in this research project. You will be given a pedometer, snacks at each class, as well as prizes and incentives such as gift certificates to local businesses in the community. In addition, there will be day care available if you have young children that need to be watched while you are attending class.

### **CONFIDENTIALITY**

Records of participation in this research project will be kept confidential to the extent permitted by law. However, federal government regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies involving human subjects) may inspect and copy records pertaining to this research. It is possible that these records could contain information that personally identifies you. In the event of any report or publication from this study, your identity will not be disclosed. Results will be reported in a summarized manner in such a way that you cannot be identified.

### **VOLUNTARY PARTICIPATION**

Taking part in this research study is voluntary. You may choose not to take part at all. If you agree to participate in this study, you may stop participating at any time. You will not be dropped from the study if you miss a class. If you choose to drop out of the study your partner with diabetes may recruit a second support person. Involvement in this study requires that you fill out questionnaires. You are free to skip any questions that you would prefer not to answer. If you decide not to take part, or if you stop participating at any time, your decision will not result in any penalty or loss of benefits to which you may otherwise be entitled. Any data collected from you prior to withdrawal may be included in the study results.

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**QUESTIONS**

Questions are encouraged. If you have any questions about this research project, please contact:

Dr. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

OR

Bev White (541) 737-9190, [bwhite@meritel.net](mailto:bwhite@meritel.net)

OR

Ruby Ibarra (503) 988-3663 x 83991, [rubilia.a.ibarra@co.multnomah.or.us](mailto:rubilia.a.ibarra@co.multnomah.or.us)

If you have any questions about your rights as a participant, please contact the Oregon State University Institutional Review Board (IRB) Human Protections Administrator, at (541) 737-3437 or by e-mail at [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu).

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Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date)

**RESEARCHER STATEMENT**

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

Researcher's Name (printed): \_\_\_\_\_

\_\_\_\_\_  
(Signature of Researcher)

\_\_\_\_\_  
(Date)

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**Nutrition and Food Management**  
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## **DOCUMENTO DE INFORMACIÓN Y CONSENTIMIENTO** **(Participante de apoyo)**

Título del proyecto: **Investigación de diabetes en la familia hispana**

Investigadores: **Melinda M. Manore, Ph.D., R.D. & Bev White R.D., M.S.**  
**Departamento de Nutrición y Administración de Alimentos**  
**de la Universidad del Estado de Oregón**

Persona de contacto del  
Condado Multnomah: **Ruby Ibarra**

### **PROPÓSITO**

El propósito de este estudio de investigación es determinar si un programa de educación sobre la diabetes, en el que usted participa como persona de apoyo, puede ayudar a su compañero(a) con diabetes a controlar su enfermedad. Su rol en este estudio de investigación es ayudar a su compañero(a) con diabetes a hacer cambios saludables en su estilo de vida. El programa de educación incluirá información sobre dieta, actividad física, y cuidado personal del propio diabético. Nuestra meta es que la persona a quien usted está ayudando y que tiene diabetes pueda mejorar sus factores de riesgos de diabetes (por ejemplo, dieta y actividad física) y sus evaluaciones de laboratorio (glucosa en la sangre, lo cual significa azúcar en la sangre, e insulina), siguiendo el programa de educación. Si se tuviera éxito, este programa tiene el potencial de mejorar la salud en general de la persona diabética que usted está ayudando y de ser implementado en otros condados de Oregón.

El propósito de este documento de consentimiento es darle la información que usted necesitará para ayudarlo a decidir si participará o no en el estudio. Por favor léalo cuidadosamente. Usted podrá hacer cualesquiera preguntas acerca de la investigación, qué es lo que se le pedirá que haga, los posibles riesgos y beneficios, sus derechos como voluntario, y cualquiera otra pregunta acerca de la investigación o de algo que no esté claro en este formulario. Cuando todas sus preguntas hayan sido contestadas, usted puede decidir si quiere o no participar en este estudio. Este documento se llama "Documento de información y consentimiento". Se le entregará una copia para sus archivos.

Lo invitamos a participar en este estudio de investigación porque usted es la persona de apoyo de una persona hispana que padece diabetes. Además, usted tiene por lo menos 19 años de edad. Hombres y mujeres que están sirviendo de apoyo, con edad mínima de 19 años. Si usted mismo padece de diabetes, se le pedirá que sea parte de la población diabética para este estudio en calidad de paciente, para lo cual será necesario llenar un documento de información y consentimiento adicional.

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## **PROCEDIMIENTOS**

Si usted está de acuerdo en participar, necesitará visitar la clínica local de salud en su condado una vez por semana (\_\_\_\_\_ día/ hora), por 12 semanas para asistir a un programa de educación con su compañero(a) que tiene diabetes. Cada sesión durará ~ 120 minutos. Este programa será impartido en español por un trabajador de la salud de la comunidad. La asistencia es de vital importancia ya que cada semana se discutirá un tópico nuevo. Se registrará su asistencia y la de la persona con diabetes a la que está apoyando. Este programa de educación comenzará en febrero de 2005.

En la primera y última clases se le presentarán dos cuestionarios en los que se le harán preguntas referentes a su relación con la persona que tiene diabetes a la que usted está apoyando. En total, usted contestará dos cuestionarios (uno en la primera clase y otro en la última). Las semanas de la 2a., hasta la 11a., estarán dedicadas al programa de educación en donde usted podrá aprender acerca de la dieta, actividad física y el cuidado personal para el control del diabético.

El horario y los procedimientos que siguen están comprendidos en este estudio:

### **1a. Semana** (de 120 minutos)

- Se presentará en su clínica local, con su compañero(a) que tiene diabetes.
- Usted contestará referente a su relación con la persona que tiene diabetes y que usted está apoyando y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar el cuestionario.

### **De la 2a. semana hasta la 11a.** (De 120 minutos para cada clase)

- Estas clases serán ofrecidas una vez por semana el mismo día de la semana y a la misma hora.
- Se presentará un programa educativo acerca de cómo mejorar la dieta, actividad física, y propio cuidado personal de su compañero(a) con diabetes.
- En la segunda clase usted recibirá un podómetro (aparato para medir cuánto camina cada día) y se le darán instrucciones para su uso.
- Se le recomendará que cuando no esté en clase camine con su compañero(a) que padece de diabetes, y para que lleve un diario para anotar sus pasos dados cada día.

### **Semana 12a.** (De 120 minutos)

- Usted y su compañero(a) con diabetes se presentarán a su clínica local.
- Usted llenará un cuestionario referente a su relación con la persona con diabetes a quien está ayudando y se le ofrecerá un refrigerio apropiado para diabéticos.
- Si fuere necesario, usted recibirá ayuda de un traductor para llenar el cuestionario.

Una vez que el proyecto esté completo, nos comunicaremos con usted para que asista a una sesión de seguimiento y será informado de los resultados del estudio. Si no le fuere posible asistir, los resultados le serán enviados por correo.

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**RIESGOS**

Los riesgos o incomodidades con los procedimientos de este estudio son mínimos. Posiblemente usted experimente alguna incomodidad emocional cuando esté llenando los cuestionarios. Para reducir esta incomodidad, usted llenará los cuestionarios lejos de otras personas, con un traductor que estará cerca de usted para atenderlo en cualesquiera preguntas o inquietudes que usted tenga. Todos los cuestionarios son confidenciales y no serán criticados.

**BENEFICIOS**

Los potenciales beneficios personales que pueden ocurrir como resultado de su participación en este estudio son los siguientes:

- Mayor conocimiento acerca de la diabetes y formas de mejorar la salud de la persona con diabetes que está apoyando.
- Un podómetro para su uso después del estudio.
- Mejoras en los factores de riesgo por complicaciones por diabetes de su compañero(a) con diabetes.

Los investigadores dan por anticipado que la sociedad podrá ser beneficiada con este estudio al ayudar a reducir la incidencia de diabetes y su costo económico, y a mejorar la calidad de vida de todas aquellas personas que tengan o estén en riesgo por la diabetes.

**COSTOS Y COMPENSACIONES**

Usted no recibirá pago alguno por participar en este estudio. Hay costos mínimos (transporte) por participar en este proyecto de investigación. Se le entregará un podómetro, bocadillos en cada clase, así como premios e incentivos, tales como certificados de regalo de comercios locales en la comunidad. Además, habrá cuidado de niños disponible si usted tiene niños que necesiten ser atendidos mientras usted está asistiendo a clase.

**CONFIDENCIALIDAD**

Los registros de participación en este proyecto de investigación serán guardados en forma confidencial por el tiempo que permita la ley. Sin embargo, las agencias reguladoras del gobierno federal y la Junta Examinadora Institucional de la Universidad del Estado de Oregon (Oregon State University Institutional Review Board) - un comité que examina y aprueba los estudios de investigación que involucran tópicos humanos - pueden inspeccionar y copiar registros pertinentes a esta investigación. Es posible que estos registros pudieran contener información que lo identifique personalmente a usted. En el eventual caso de cualquier informe o publicación de este estudio, su identidad no será dada a conocer. Los resultados serán informados de manera resumida, de tal manera que usted no podría ser identificado.

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**PARTICIPACIÓN VOLUNTARIA**

Tomar parte en este estudio es una decisión voluntaria. Usted puede escoger no tomar parte. Aun si usted está de acuerdo en participar en este estudio, puede dejar de hacerlo en cualquier tiempo. Si usted decide salirse del estudio, su compañero(a) con diabetes puede reclutar a otra persona para que lo sustituya a usted. El involucrarse en este estudio requiere que usted llene algunos cuestionarios. Siéntase en libertad de no contestar cualesquiera preguntas si prefiere no contestarlas. Si decide no tomar parte, o si prefiere no seguir participando en cualquier momento, su decisión no será motivo de multa alguna ni de pérdida de beneficios a los cuales usted pudiera tener derecho. Otros datos obtenidos sobre usted antes de su retiro del proyecto podrían ser incluidos en los resultados de este estudio.

**PREGUNTAS**

Las preguntas son bien recibidas, por lo que le recomendamos que las haga si tiene algunas dudas. Si tiene preguntas acerca de este proyecto de investigación, por favor comuníquese con:

Dra. Melinda Manore (541) 737-8701, [melinda.manore@oregonstate.edu](mailto:melinda.manore@oregonstate.edu)

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Bev White (541) 737-9190, [bwhite@meritel.net](mailto:bwhite@meritel.net)

O

Ruby Ibarra (503) 988-3663 x 83991, [rubilia.a.ibarra@co.multnomah.or.us](mailto:rubilia.a.ibarra@co.multnomah.or.us)

Si tiene preguntas acerca de sus derechos como participante de apoyo, por favor comuníquese con el Administrador de las Protecciones Humanas (Human Protections Administrator) de la Junta Examinadora Institucional de la Univesidad de Oregon (Oregon State University Institutional Review Board (IRB) en el número telefónico (541) 737-3437 o por el correo electrónico [IRB@oregonstate.edu](mailto:IRB@oregonstate.edu).

Su firma indica que este estudio de investigación le ha sido explicado, que sus preguntas han sido contestadas, y que está de acuerdo en participar en este estudio. Se le entregará copia de este formulario.

Nombre del participante de apoyo (en letra de imprenta): \_\_\_\_\_

\_\_\_\_\_  
(Firma del participante de apoyo)

\_\_\_\_\_  
(Fecha)

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**DECLARACIÓN DEL INVESTIGADOR**

He discutido con el participante de apoyo los puntos antes mencionados o, donde era apropiado, con su representante legalmente autorizado y, cuando fue necesario, usando los servicios de un traductor. En mi opinión, el participante entiende los riesgos, beneficios, y procedimientos involucrados con su participación en este estudio de investigación.

Nombre del Investigador (en letra de imprenta):

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(Firma del Investigador)

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(Fecha)



## Appendix 10

ACCULTURATION OF PARTICIPANTS  
HISPANIC FAMILY DIABETES PROJECT

Class session: \_\_\_\_\_ (1<sup>st</sup>, 2<sup>nd</sup>, or 3<sup>rd</sup>)

1. In general, what language(s) do they read and speak?

Only Spanish  
Spanish better than English  
Both equally  
English better than Spanish  
Only English

2. What language(s) do they usually speak at home?

Only Spanish  
Spanish better than English  
Both equally  
English better than Spanish  
Only English

3. What language(s) do they usually speak with their friends?

Only Spanish  
Spanish better than English  
Both equally  
English better than Spanish  
Only English

4. Born in U.S.?

5. If not born in U.S., length of residence in U.S. -  $< 3$  years or  $\geq 3$  years.

6. If not born in U.S., age of arrival to U.S. -  $< 25$  years old or  $\geq 25$  years old.

## Appendix 11

## Hispanic Family Intervention Attendance Record

# HISPANIC FAMILY INTERVENTION ATTENDANCE RECORD

County \_\_\_\_\_

Class location \_\_\_\_\_

Instructor: \_\_\_\_\_

✓ - attended  
 ⊘ - did not attend

[illegible]

Appendix 12  
**WEEKLY PROCESS CHECKS – FOR CLASS INSTRUCTORS**  
 Hispanic Family Intervention

Class Date	
Instructor(s)	
Location of Class	
Number of attendees	
Lesson Topic (s):	

Were you able to cover the entire lesson for the class?

Were there any problems that arose in teaching this week's curriculum? If so, what? What did you do to resolve those issues?

What study outcome measures did you review or discuss in the lesson? Please check all that apply

- ☐ Increase fruit/veggie
- ☐ Increase whole grains
- ☐ Decrease saturated fat intake
- ☐ Increase physical activity
- ☐ Self-monitoring of blood glucose

What types of questions did participants ask? Were you able to answer these questions successfully, do you need more information in a particular area?

What worked well that you would replicate in the future?

What changes would you make in the future?

Additional observations or comments (please make comments on back of this page).