Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes

BY

AMPARO DEL SOCORRO CASTILLO
M.D., Javeriana University, Bogota, Colombia, 1982
M.S., Maharishi University of Management, Fairfield, IA, 1994

THESIS

Submitted as partial fulfillment of the requirements
for the degree of Doctor of Philosophy in Public Health Sciences
in the Graduate College of the
University of Illinois at Chicago, 2016

Chicago, Illinois

Defense Committee:

    Laurie Ruggiero, Community Health Sciences, Chair and Advisor
    Naoko Muramatsu, Community Health Sciences
    Loretta Quinn, College of Nursing
    Benjamin Gerber, College of Medicine
    Michael Berbaum, Epidemiology and Biostatistics

I dedicate this thesis to my dear husband, Sam. His love and support inspired and sustained me.

ACKNOWLEDGEMENTS

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SUMMARY

This study evaluated the feasibility and effectiveness of a 12-week Tai Chi program for Hispanic older adults with diabetes. Forty self-identified Hispanic men and women participated in a randomized controlled pilot that used a cross-over design and a wait-list control group. Participants were recruited from churches, community centers and senior residences in South Chicago. Those assigned to the treatment group received Tai Chi instruction twice per week at a community clinic that offered easy access and free parking. The control group met once per month at the community clinic and received health advice. At the end of the 12-week period, the control group received Tai Chi instruction. The study evaluated the receptivity and acceptability of Tai Chi, blood glucose levels, blood pressure, and psychosocial stress, including diabetes-related distress, perceived stress, and immigration-related stress. Co-variates included social support, medication adherence, self-care behaviors, physical activity self-efficacy and self-reported numbers of physically and mentally healthy days. The comparison between the treatment and control groups did not show significant differences on any of the study outcomes. Secondary pre-posttest analyses of all those participants who received the Tai Chi intervention showed a significant improvement on levels of blood glucose, diabetes distress, and extra-familial stress. Participants reported good receptivity and acceptability of Tai Chi, with the number of practice hours significantly predicting blood sugar levels at post-test. These results warrant further study.

I. INTRODUCTION

According to the Institute of Medicine, the number of older adults in the U.S. in 2009 was 39.6 million (12.4% of the population) and that number is expected to climb to 72.1 million (19% of the population) by the year 2030 (Institute of Medicine, 2008). Similarly, the Hispanic/Latino population is projected to increase from 50 million in 2011 to 106.2 million in 2050 (US Census Bureau, 2010), and its population of adults older than 65 is expected to increase by 224%, outpacing the growth of the white population of the same age (Greenberg, 2009).

Currently, diabetes is the seventh leading cause of death and disproportionately affects Hispanic/Latinos and older adults (Centers for Disease Control and Prevention [CDC], 2014). It is estimated that around 29 million people have diabetes in the US, including 8.1 of people without a confirmed diagnosis of the disease (CDC, 2014). Death rates among persons with diabetes are 1.5 times those of people without diabetes (CDC, 2014). Among people 20 years and older, 12.8% of Hispanic/Latinos are diagnosed with diabetes compared to 7.6% of non-Hispanic Whites (CDC, 2014). Although recent analyses of epidemiological trends have identified a leveling off of the incidence and prevalence of diabetes in the general population between 2008 and 2012, there remains a significant increase in incidence among Hispanic groups (Geiss, Wang, Cheng, Thompsons, Barker, Li, et al., 2014). Since age is one of diabetes important non-modifiable risk factors, diabetes prevalence is high in the population older than 65 (Cowie et al., 2009). This population also experiences high levels of co-morbid conditions (micro- and macro-vascular disease, depression, etc.) and disability that significantly affect its quality of life (Corriere, Rooparinesingh, & Kalyani, 2013). The combination of a high incidence of disease, a large aging population and high levels of co-morbidity and disability represent significant costs to public health (American Diabetes Association [ADA], 2013). The American Diabetes Association estimated that the cost of diabetes care climbed 41% in only five years, from 174

billion in 2007 to 245 billion in 2012 (ADA, 2013). This represents a very important burden for the individual and the system.

Self-management is the cornerstone of diabetes treatment. Hispanics/Latinos show high levels of non-compliance with diabetes self-care practices (Kirk, Graves, Bell, Hildebrandt, & Narayan, 2007; Mutchler, Bacigalupe, Coppin, & Gottlieb, 2007) and spend fewer days in self-care activities than Whites (Trief, Izquierdo, Eimicke, Goland, Palmas, & Weinstock, 2013). Several factors affect self-care, particularly low income and education, lack of access to care, and cultural and linguistic barriers (Mutchler, et al., 2007). Hispanics are also susceptible to developing depression related to uncontrolled diabetes, and hence to neglect self-care practices.

Psychosocial stress impacts blood glucose levels directly and indirectly. Especially in type 2 diabetes, glucose levels are reactive to stress hormones (ADA, 2007). Persons with diabetes experience stress more frequently than the general population and thus are more susceptible to depression and poor adherence to a self-care regimen. Stress interferes with the performance of diabetes related self-care tasks, such as glucose monitoring, exercising, or healthy eating (Peyrot, McMurry & Kruger, 1999). Psychosocial stress affects Hispanic/Latino groups of low socio-economic status, and is expressed in high levels of depression and low levels of treatment compliance. The survey Stress in America conducted by the American Psychological Association (APA, 2012) finds that a greater percentage of Hispanic/Latinos report higher levels of stress (50%) compared to the previous year (44%); and that money is a more significant source of stress for Hispanic/Latinos (77%) than Whites (68%). According to the Pew Hispanic Center, from 2006 to 2010 the poverty rate among Hispanic/Latinos increased from 20.6 to 26.6% compared to whites (8.2 to 9.9%, respectively). In addition, for a large number of Hispanic/Latinos, acculturative stress and concerns related to immigration status are significant stressors (Cavazos-Rehg, Zayas, & Spitznagel, 2007). Although the number is larger among the foreign-born

(72%), up to 35% of the native-born Hispanic/Latinos also report concerns about deportation according to a survey by the Pew Hispanic Center (2008).

The above facts have important implications for the development of interventions and policies designed to meet the growing demands of the older adult population. Health education is fundamental to the successful treatment of diabetes. Behavioral interventions aiming at primary and/or secondary prevention of type 2 diabetes commonly incorporate dietary and physical activity approaches, but stress management is not routinely included (Chodosh, Morton, Mojica, Maglione, Suttorp, Hilton, et al., 2005). Although physical activity has demonstrated health benefits for older adults and persons with diabetes including positive stress reduction effects (Sigal, Kenny, Boulé, Wells, Prud'homme, Fortier, Reid, et al, 2009), Hispanic/Latinos show low compliance with such recommendations (Marquez, McAuley, & Overman, 2004). Older adults prefer the practice of low impact physical activity over aerobic or resistance exercise (Marquez et al., 2004).

I propose that behavioral interventions for Hispanic/Latino older adults with diabetes should address the stress-related component as well as the cognitive/instructional component if they are to promote reduction of risk factors, successful self-care management and improvement in quality of life. Such interventions should also be amenable to adaptation and replication at low cost, and easily sustainable in community settings.

One intervention that has demonstrated such impact on older adults is Tai Chi. An increasing amount of evidence supports an association between the practice of Tai Chi and improvement in mental health, emotional well-being and stress reduction (Taylor-Pillae, Haskell, Waters, & Froelicher, 2006). Also, Tai Chi can successfully improve insulin resistance (Tsang, Orr, Lam, Comino, & Singh, 2008) and reduce blood glucose levels (Yeh, 2007). The ancient Chinese martial art of Tai Chi is a

combination of gentle flowing movements with deep breathing, relaxation and meditation. It is

considered low impact, moderate exercise because demands less than 55% of maximal oxygen intake,

and can benefit balance and cardio-respiratory function in older adults (Bronas, Treat-Jacobson, &

Painter, 2009; Lu & Kuo, 2003; Tsang Orr, Lam, Comino, & Singh, 2004; Wang, et al, 2004). It is

considered equivalent to the amount of moderate-intensity aerobic physical activity normally

recommended for type 2 diabetes, at 50-70% maximum heart rate (ADA, 2008; Lee, Pittler, Kim, &

Ernest, 2008). Its practice has become very popular because it does not require equipment and can be

adapted to groups with disabilities. With the help of an instructor, the regular daily practice of Tai Chi

may be an effective secondary prevention technique for diabetes self- management.

To address the important issues of cultural competence, I conducted a series of focus groups

assessing among other issues, the receptivity of Hispanic/Latino older adults to Tai Chi. The results shed

some light on the barriers and supporting factors for the practice of physical activity, the impact of social

support, their perception of Tai Chi and their preferences for the implementation of Tai Chi classes.

Twenty seven (8 men; 19 women) Hispanic/Latino older adults 50 to 80 years of age, with

diagnosed type 2 diabetes participated in six focus groups in the Spring and Summer of 2011. Physical

activity was the most popular form of stress relief. Nineteen participants reported walking, running,

dancing, doing aerobics and gardening.

Social support was consistently reported to alleviate stress and to help in the practice of physical

activity. Help with transportation; motivation to engage in exercise; useful recommendations and advice

from family members and friends; and emotional support in the form of encouragement,

accompaniment, and facilitating catharsis (stress relief), were most frequently reported.

Barriers for physical activity included: work schedule among those employed; family commitments and their associated gender roles, particularly for women; physical limitations due to age or diabetes complications; outdoor conditions related to bad weather, lack of neighborhood safety, difficult access to facilities due to cost or to physical limitations; perceived language barriers; and women's concern for what their husbands or others might think of their exercise practice.

The main motivator for physical activity was the support of children or friends; good weather; access to exercise classes; perceived health benefits of the activity; reduced need for medication and improvement in sex life (particularly among men); and having exercise in groups (instead of individual sessions). Participants reported little experience with formal stress management, but were receptive to Tai Chi, dance, yoga, massage, meditation, Reiki. Their recommendations for implementation included: modifications to suit physical limitations or disabilities; to have an instructor for guidance and demonstration of the moves, and to have group classes in Spanish. They considered Tai Chi to be particularly suited for patients who cannot strain, and tailored for their age; Tai Chi was perceived as beneficial for relaxation and stress reduction.

Applying the psycho-physiological model of diabetes (Peyrot et al., 1999), this document presents physical activity with Tai Chi as a viable intervention to address the psychological and physiological needs of a high risk group of Hispanic/Latino older adults with type 2 diabetes. Incorporating the recommendations from the focus groups, I evaluated the feasibility of implementing Tai Chi as an acceptable form of physical activity among Hispanic/Latino older adults. Tai Chi was also assessed on its potential to impact physiological markers of diabetes (hemoglobin A1C, psychosocial stress and blood pressure) on 49 participants. The Tai Chi intervention was conducted over 12 weeks at an easily accessible community location, and under the direction of a certified bilingual instructor. The data analysis compared the Tai Chi intervention to a wait-list group receiving health advice, and also

evaluated baseline and post-intervention differences on both physiological and behavioral markers of diabetes.

This study proved the feasibility of Tai Chi for the Hispanic/Latino elderly, and showed promise in its capacity to positively affect psychosocial stress and glycemic levels for those with type 2 diabetes. As a form of exercise, Tai Chi may provide physiological and psychological benefits for the growing number of Hispanic/Latino older adults with high exposure to stress; and it should not be overlooked as a strategy that can be successfully adapted to different cultural groups with minimal investment and potential high preventative impact.

A.   **Background**

    1. Epidemiology of Diabetes

Diabetes is the seventh leading cause of death in the U.S. Mortality rates among persons with diabetes are 1.5 times those of people without the disease (CDC, 2014). It is estimated that 29.1 million Americans suffer the disease, with 8.1 million remaining undiagnosed (CDC, 2014). Since 1980, the number of cases of type 2 diabetes in adults aged 18 years or older increased more than five times, going from 5.5 million to 29.1 million by 2012, the equivalent of 9.3% of the U.S. adult population (CDC, 2014). Prevalence of diabetes increases with age, and it is highest among those 65 years and older (Geiss, et al., 2014). In this age group, 25.9% of the population is considered to have diabetes, compared with 16.2% in the group of 45 to 64 years olds (CDC, 2014). However, analyses of trends show that prevalence increases at a higher rate among the 20 to 44 year olds compared with the other two age groups (Geiss, et al., 2014).

From 1980 to 2009, new cases of diabetes per year increased from 493,000 to more than 1.8 million (CDC, 2013). These increases that paralleled the increases in prevalence, suggest that the

majority of the change is not due to the aging of the population. Until recently, incidence has been higher among those 65 years and older. In 2007, incidence rose among those 45-64 years of age to a level similar to those older than 65; in 2008 and 2009, 45-64 year olds showed higher incidence (14.3 and 15.2%, respectively) than the older age group (12.2 and 11.6%, respectively) (CDC, 2013).

Among people 20 years and older, 12.8% of Hispanic/Latinos are diagnosed with diabetes compared to 7.6 % of non-Hispanic Whites (CDC, 2014). The rates are higher among the Mexican-American and Puerto Rican subpopulations with 13.9% and 14.8% of them, respectively, diagnosed with diabetes (CDC, 2014). The percentage of Hispanics with diagnosed diabetes increased from 6.3% in 1997 to 8.4% in 2009, an increase of 33.3%. Age-adjusted incidence in 2009 was 13.1 per 1,000 among Hispanics compared to 8.5 per 1,000 among whites (CDC, 2013). Similarly, in 2008, the median age at diagnosis among adults with diabetes was 53.2 years for whites and 49.7 years for Hispanics. Recent analyses of epidemiological trends identified a leveling off of the incidence and prevalence of diabetes in the general population between 2008 and 2012 (Geiss, et al, 2014). However for groups with low levels of education (high school diploma or less) and for Hispanic/Latinos prevalence continues to climb; a significant increase in incidence also remains for Hispanic/Latino groups (Geiss, et al, 2014).

Important risk factors for diabetes like obesity, lack of physical activity, poor dietary habits and stress are higher among racial and ethnic minorities and groups with low levels of education. Latinos have a 1.5 increased risk of developing diabetes when compared to their non-Hispanic white counterparts (CDC, 2013).

The older adult population experiences high levels of co-morbid conditions (micro- and macro-vascular disease, depression, etc.) and disability that significantly affect their quality of life (Corriere et

al., 2013). The combination of a high incidence disease, a large aging population and high levels of co-morbidity and disability represent significant costs to public health (ADA, 2013). The American Diabetes Association estimated that the cost of diabetes care increased by 41% in only five years, from 174 billion in 2007 to 245 billion in 2012 (ADA, 2013). This represents a very important burden for the individual and the system.

2. Effects of Stress on Glucose Levels and Insulin Resistance

Type 2 diabetes is a metabolic condition characterized by elevated levels of circulating glucose in the presence of insulin resistance. The development of type 2 diabetes follows a sequence of events that involves in the initial stage the development of insulin resistance related to obesity or physical inactivity with compensatory increased production of insulin by beta cells to maintain normal levels of glucose. In the second stage, insulin resistance increases with impairment of glucose uptake by the skeletal muscle but the pancreas maintains hyperinsulinemia. In the third stage, there is further increase in insulin resistance but glucose levels increase because of reduced control over glucose production by the liver. The beta cell is affected by high glycemic levels and insulin production declines. The increase in insulin resistance favors an increase in fatty acids. Hyperglycemia triggers several pathways that lead to diabetes complications. Significant among those mechanisms are the oxidative and glycation processes that lead to endothelial dysfunction, LDL oxidation and atherosclerosis (Quinn, 2002).

The mechanisms of diabetes and stress coincide at several points in the processes, and have a synergistic effect in precipitating endothelial dysfunction and its related complications. Stress may be defined as the state of threatened homeostasis provoked by a psychological, environmental or physiological threat to well-being or homeostasis; chronic stress is the long term repeated disruption of the homeostatic system (Rosmond, 2005). Real or perceived danger triggers a concerted response that involves the hypothalamic-adrenal-pituitary (HPA) axis and sympatho-adrenal system, with autonomic,

immune and behavioral responses in what is called the *stress response*. Repeated exposure to stressors leads to negative physiological responses including endothelial dysfunction and a generalized inflammatory response, with long lasting effects. The actions of stress hormones (epinephrine, norepinephrine and cortisol) are usually opposed by insulin which has vasodilatory functions but chronic stress favors the development of insulin resistance and impairs the balancing effect (Black, 2003). Cortisol for example, elevates glucose levels, releases lipids and breaks down proteins. It also inhibits the immune system, and facilitates the effects of catecholamines (norepinephine, epinephrine) on the cardiovascular system, inducing vasoconstriction and increasing heart rate (Rosmond, 2005). The combined effects of insulin resistance and chronic exposure to stress hormones lead to glucose intolerance and hyperglycemia, compensatory hyperinsulinemia, hyperlipidemia, high blood pressure, weight gain, visceral adiposity, and ultimately diabetes, hypertension and cardiovascular disease (Dickerson & Kemeny, 2004).

a. <u>Psychological impact</u>

Although many circumstances may facilitate negative feeling states, external threats to the goal of physical self-preservation or preservation of the social self elicits cortisol changes and the mobilization of energy resources in the typical "fight or flight" response (Dickerson & Kemeny, 2004). According to Dickerson, humans strive to preserve the social self that reflects one's social value, esteem and status. Social evaluative threats and uncontrollability of the environment are the main factors eliciting stress activation of the HPA system. These are exemplified by conditions in which the individual cannot avoid negative consequences or cannot succeed despite best efforts, such as those associated with low socio-economic status, or social discrimination. Greater effects are present when outcomes of the uncontrollable condition impede advancing toward a central goal (Dickerson, Gruenwald, & Kemeny, 2004). These repeated experiences contribute to high cholesterol levels, atherosclerosis, etc. (Black, 2003). Minority groups with low socio-economic status in the US

experience high levels of chronic psychosocial stress associated with increased morbidity and mortality risk and elevated levels of A1C across different cultural/ethnic groups (Kirk et al., 2007). Social rejection and/or the perception of rejection from the environment are associated with increased morbidity and mortality. Studies in African Americans find that stress of internalized racism is associated with depression, anxiety, abdominal obesity and increased risk of abnormal glucose tolerance test (Black, 2003; Boyle et al., 2007; Dickerson, et al., 2004).

Studies of Latinos also link discrimination with negative health outcomes, namely psychosocial distress, anxiety and depression (Lee & Ahn, 2012). Anxiety and somatic complaints are expressed in Latino college students experiencing discrimination. Studies show that about 50% of all Latinos report experiences of discrimination on almost daily basis (Perez, Fortuna, & Alegria, 2008) Perceived discrimination is more often reported by young, male, English speaking, second generation Hispanic/Latinos, with higher education. Older adults seem to be less exposed than other age groups (Sirin et al., 2015). In their study, Sirin et al. found that discrimination-related stress predicted three mental health outcomes: withdrawn-depressed, anxious-depressed and somatic symptoms. Other studies have also associated the experience of discrimination with physical outcomes and with problem behaviors (Boyce & Fuligni, 2007; Vega & Rodriguez, 2010). Most of these studies have evaluated discrimination-related stress in youth and college students. There is a dearth of information on the experience of discrimination and its effects on Hispanic/Latino older adults.

b. **Behavioral impact–Effects of stress on glycemic control**

Stressors affecting the patient with diabetes include the anxiety and fear associated with the diagnosis, the impending changes in familiar routines, and the frustration involved in trying and failing at new behaviors, or the onset of complications that limit autonomy and quality of life. But other types of stress not diabetes-related, will affect the patient with diabetes just the same, such as financial

worries, unemployment, loss of dear ones, etc. Stressors appearing in the life of a person with diabetes will generate momentary, transient or chronic variations in glycemic levels (Peyrot et al., 1999). Blood glucose levels vary constantly within a homeostatic range. In a person with diabetes this homeostasis is disrupted and wide variations may occur. Glycemic levels respond exquisitely to stress processes. Momentary processes (daily hassles) generate acute changes in glycemia that are measurable at this level by self-monitoring with a glucose meter. Transient stressors or life events such as psychosocial factors (financial loss, etc.) that are more stable than the momentary events, affect levels of glycemia that are measured by the concentration of glycosylated hemoglobin (A1C) in blood. Chronic stressors such as chronic financial stress, or stressors eliciting HPA activation that persists after their withdrawal, operate at longer time frames. The glycemic levels affected by these chronic events are more accurately tracked by multiple measures of A1C or self-monitored glucose over long periods of time (Peyrot, 1999). Maintaining levels of A1C at or below 7% is associated with minimal levels of diabetes-related complications and mortality (ADA, 2015). Besides the direct effect that stress has on the physiology by affecting blood glucose and A1C levels, stress indirectly affects glycemic control by altering the ability to perform the behavioral routines required by the self-care regimen, thus modulating the relationship of diabetes and regimen adherence (Peyrot et al., 1999). Increasing levels of stress make it difficult for patients to adhere to diet restrictions and self-monitoring schedules, maintain exercise routines, or sustain the coping strategies that help to relieve stress. Peyrot and colleagues has found that among other factors, positive coping styles are important determinants of glycemic control.

A literature review by Fisher, Thorpe, McEvoy DeVellis, & DeVellis (2007) evaluated 186 articles to identify promising or effective healthy coping interventions and areas of needed research. The article focused on therapies provided within the context of the medical care setting such as psychotherapy, cognitive therapy, etc., and did not include informal approaches mentioned above (prayer, denial, etc.). The review confirmed the important impact of diabetes, diabetes treatment and

metabolic control on quality of life, as well as the effect of psychosocial factors on metabolic control. It also found that cognitive behavioral therapy and coping/problem solving interventions as well as self-management interventions that incorporate support and attention to emotional factors, improved quality of life and metabolic control (Fisher et al., 2007).

3. Stress and Aging

Age is one of the most important non-modifiable risk factors for diabetes. The American Diabetes Association (2010) recommends initiating testing for diabetes in asymptomatic individuals at 45 years of age. The highest prevalence and incidence of diabetes occur among the age group 65 and older (CDC, 2015). At the physiological level stress, aging and diabetes co-occur when higher levels of glucose in the elderly appear with the elevation of corticosteroids and catecholamines due in part, to the loss of cells in the hippocampus responsible for the down regulation of corticoid production (Black, 2003). Although stress and aging are usually associated, the experience of stress does not start during the later span of life but rather unfolds throughout the life course becoming an indistinguishable part of development and aging. One of the most common manifestations of stress among the elderly is depression or depressive symptoms (Cole & Dendukuri, 2003). In their study of late-life depression, Yang (2007) found that the common association of depression with aging, is in reality confounded by factors such as physical functioning, economic well-being and education. What is considered the result of aging is actually the manifestation of earlier experiences and stressors that extend their effects well beyond the younger years. The life course perspective lays the basis for the understanding of current stressors in light of previous experiences. A background of relentless hardships such as poverty sets the stage for other simultaneous, sequential or overlapping stressors. These stressors become determinants of the quality of life of older people. Several of these potential stressors precede the elder years, persist throughout and have the potential to detract from quality of life and contribute to health disparities in later life. Disparities in economic status, education and general opportunity build on earlier life

experiences (Pearlin, Schieman, Fazio & Meersman, 2005).

Stressors among the elderly differ from those of the younger adults (Pearlin & McKean Skaff, 1996). Eventful stressors such as getting divorced, losing a job, problems with the law, etc., tend to diminish in the older years since the organization of older people's lives reduce their exposure. Two kinds of eventful stressors are still salient with advancing age. They are the onset of illness or physical limitations, and the death of loved ones, particularly their peers. Older people become more aware of their physical frailty and their surroundings. They may become more apprehensive about their safety, more sensitive to changing neighbors and neighborhoods, including the declining physical condition, and restrictions in access to facilities, transportation, amenities and health care services. Family conflicts and the relative loss of control over their children's lives may explain their disengagement from family affairs. Health and financial problems that may be associated with loss of status are also powerful sources of stress. But very importantly, activities of daily life become stressful as physical disabilities and frailty progress (Pearlin & McKean Skaff, 1996).

4. <u>Stress in Hispanic/Latinos</u>

Hispanic/Latinos in the US experience a unique set of conditions similar in some ways to those experienced by African Americans, but with the added complexities associated to language diversity, immigration and acculturation. Hispanic/Latinos living with diabetes in the U.S. may then need to address another set of stressors associated with the disease. These stressors may be grouped into three categories: **Social stressors** such as those common to other minority groups like low socio-economic status, low levels of education, under/unemployment, lack of access or inadequate health care; **Ethno-cultural stressors** related to the experience of being Latino in the U.S. such as ethnic/racial discrimination, linguistic barriers, acculturation stress, undocumented status, conflicting health beliefs, family/gender roles, etc.; and **Diabetes-specific** or stressors related to the diagnosis of the disease, low

diabetes health literacy, adoption of behavioral changes; experience of complications (depression, hypoglycemia, vision loss, foot complications) and treatment. **Social stressors:** Low income and low education are associated with poor quality of health services and poor diabetes self-management. Hispanics report lower household income compared to other groups. Up to 59% report that someone in their household has been without a job in the past year; and up to 75% consider that their personal finances are in "fair" or "poor" condition (Pew Hispanic Center, 2012). Latinos are the group with the highest drop in median household wealth since 2005 (66%) compared to Blacks (53%) and whites (16%). And between 2006 and 2010, the poverty rate among Latinos increased from 20.6 to 26.6% compared to Blacks (from 24.3 to 27.4%) and whites (from 8.2% to 9.9%) (Pew Hispanic Center, 2012). They are also the minority group with the highest level of unemployment, and before the advent of the Affordable Care Act (ACA) about 40% of Latinos reported been uninsured (CDC, 2009).

Even after the implementation of the ACA, a significant number of Latinos are expected to remain uninsured (Galarneau, 2011). Compared with 88% of Whites and 79% of African Americans, 59% of adult Latinos earn a high school diploma and only 10% report completing studies to the college level (Pew Hispanic Center, 2007).

Ethno/cultural stressors: As a distinct minority group, Hispanic/Latinos in the U.S. are exposed to discrimination or racism; many immigrants experience acculturative stress and legal problems associated with their immigration status, and communication problems due to cultural and language differences (Arbona, Olvera, Rodriguez, Hagan, Linares, & Weisner, 2010; Caplan, 2007). Perception of racism among Latinos is associated with poor self-reported physical and mental health and with negative coping styles. Immigration status and acculturation are also associated with the experience of discrimination and racism (Caplan, 2007). Acculturated immigrants are more likely to perceive discrimination than acculturated US born Latinos. Immigrants should endure the process of

accommodation or assimilation to the new culture, including new language and cultural values sometimes contrarian to those in their country of origin. The collectivism, *familism* and *simpatia* that are embedded in the Hispanic/Latino social interactions are in conflict with the individualism of the host culture. Immigrants report loss of family and friends, lack of a community, and loss of social status (Caplan, 2007). These conditions favor their placement in low income, isolated communities or *barrios*. Spanish-speaking immigrants also report worse general health than English speakers, either U.S.-born or foreign-born. Undocumented immigrants report higher levels of stress than documented and U.S.-born Latinos, due to occupational hardship, fear of deportation and constant uprooting, higher rates of anxiety and depression, and negative coping with alcohol and drug abuse (Caplan, 2007; Pew Hispanic Center, 2008). Poor communication between Latino clients and health providers is related to cultural differences in understanding disease and treatments, lack of rapport with provider, and low health literacy (Hatcher & Whittemore, 2007; Schoenberg, Drew, Palo-Stoller, & Kart, 2005). For example, engaging in health practices not accepted by health providers such as the use of folk healers and remedies is prevalent among Latinos, particularly Mexican Americans (Caban & Walker, 2006).

Diabetes-related stressors: In general, Latinos consider diabetes a very serious, life- threatening illness, and have fear of the disease and the development of complications (Hatcher, 2007). "Susto" or fright, anger or a strong emotion is commonly linked to the initiation of symptoms or worsening of the disease (Hatcher, 2007; Schoenberg, Drew, Palo-Stoller, & Kart, 2005). The perception that the onset of the disease is the "will of God" is also very common, as well as a more biomedical perspective that acknowledges the influence of heredity, diet, lack of physical activity and "bad behaviors" such as drinking, smoking, drug abuse and lack of sleep (Hatcher & Whittmore, 2007). The stress related to the experience of diabetes, is also expressed at other moments throughout the disease process. Latino patients with diabetes report a sense of separation from those without the disease. They also perceive a stronger negative impact of the behavioral changes demanded by diabetes treatment than European

Americans. They claim the disease changes their mood and increase fatigue; changes their social life and relations, and bring worries about health decline, financial decline, and concerns that their children will inherit the disease. Fear of hypoglycemia is also prevalent (Hatcher, 2007). Although generally positive, the strong social support received from the family may be perceived as intrusive, overprotective and limiting (Rivera, 2003). Treatment for the disease is another cause of stress since the diet recommendations are perceived as contrary to the foods they like, making it difficult to follow, especially at family gatherings and holidays (Rivera, 2003). For many women, self-care demands may be in conflict with their perceived role in the family and they tend to give precedence to their families' needs than their own (Caban, 2008). Other sources of stress related to the disease are inadequate resources, substandard medical care, and "exposure to deleterious environments, and persistent exclusion from participation in a sustainable, meaningful and secure economic, social and political structure" (Schoenberg et al., 2005). Complications from the disease are of substantial importance in the quality of life of a person with diabetes. Among Latinos, depression is a complication of high prevalence (two-fold risk) that leads to neglect of self-care practices and poor glycemic control (Anderson, Freedland, Clouse, & Lustman2001). Hispanics/Latinos show high levels of non-compliance with diabetes self-care practices (Kirk et al., 2007; Trief et al., 2013).

5. Stress Management for Diabetes

a. Stress Management Interventions for Hispanic/Latinos

Health education programs that are culturally appropriate and based on the empowerment model have been found successful in Hispanic patients with type 2 diabetes, improving diabetes knowledge, self-efficacy and A1C levels (Brown et al., 2005). In these programs, level of exposure to health education is directly associated with improvements in A1C (dosage effect): more sessions = better outcomes (Brown et al., 2005). However, cultural competence and access to health care are deficient among Hispanic/Latinos, limiting the impact of health education programs (Mutchler et al., 2007).

There is extensive evidence of the association of depression and diabetes among Hispanic/Latinos. Besides depression, very few studies evaluate the emotional well-being in this population. A review of the literature evaluated type 2 diabetes management programs addressing emotional well-being and self-care behaviors among Latinos, described the strategies to improve physiological and mental health outcomes in diabetes and evaluated the cultural sensitivity of interventions (Concha et al., 2009). Of 13 studies included, only one study was specifically designed to improve emotional well-being among patients with type 2 diabetes. Although all of them included some cognitive outcome, only six used a psycho-cognitive theory as framework for the intervention. Eight of the studies had a randomized controlled design, and most were implemented in community settings. The most common approaches had cognitive factors as mediators, such as diabetes knowledge, health beliefs, problem solving/coping skills, and self-efficacy. The authors recommended cognitive approaches since they are important for groups with limited financial/social resources such as the Latino minority. Emotional-focused programs may help Latinos communicate their emotions and serve as preventive therapy. Ideally, the referral of patients to mental health professionals is recommended, but this strategy may not work in all settings since mental health services have been found difficult to access, provide inadequate services or lack cultural sensitivity. Incorporating an emotional problem solving/coping approach into the self-management program may be necessary to address the negative emotions that affect so many Latinos with diabetes. Applying these methods in community settings with the use of promotor as may prove more feasible and successful. The review underscores the need for research in psychosocial issues and diabetes care, and for the application of effective treatments to relieve emotional distress in patients with type 2 diabetes (Concha et al., 2009).

Coping: Among Latinos, the most common forms of coping are denial and avoidance including *fatalism* (e.g., denial of diagnosis of diabetes, venting in the presence of multiple demands, etc.) (Caban, 2006), and the very common use of prayer to regain emotional balance and to adapt to the situation

(Hatcher & Whittemore, 2007). Prayer and social support are common among Latinos of low socio-economic status (Hatcher & Whittemore, 2007). Seeking professional help was mentioned by Cherrington and colleagues as one of the problem-focused strategies in their study of co-morbid depression in Latinos with diabetes (Cherrington, Ayala, Sleath, & Corbie-Smith, 2006).

Prayer: Latinos believe that prayer helps them with their diabetes. In a sample of Mexican Americans, 77% thought that God helped their diabetes by reducing stress and anxiety (Hatcher & Whittmore, 2007). Others believe that God's role is more profound but does not interfere with accessing medical care. Implementing strategies with prayer would be well accepted. Most likely, older cohorts would rely more heavily on prayer than younger cohorts. But I would expect these differences to be associated with education and acculturation, as the older cohorts are less likely to have received formal advanced education than the younger cohorts.

Fatalism **and denial:** is the perception that life is pre-determined and nothing can change or prevent its course. Hispanics from different countries of origin seem to coincide in this attitude toward life and disease (Caban & Walker, 2006). In spite of its widespread presence there is little research about fatalistic thinking among Hispanics with diabetes. Some researchers connect fatalism with denial, while others relate it to religious faith, and still others to hopelessness (Caban & Walker, 2006). Fatalism may become a barrier to self-management or to medical care if the individual feels that things are out outside of their control, and decide not to learn about their disease. Participants residing in rural areas have more fatalistic views than those in urban areas. Fatalism may be influenced by diabetes education, social support and appropriate psychological counseling. Since it is largely related to symptoms that are out of control, a stress management approach could help to ameliorate the perceived distress. Martin and colleagues found that older cohorts presented more acceptance but not denial (Martin, Rott, Poon, Courtnay, & Lehr, 2001).

Social support: is reported frequently. Interestingly however, gender differences emerge consistently in those reports of social support. As discussed above, female gender is an important risk factor for depression. One of the reasons that may explain this finding is the fact that Latinas feel lack of social support from their immediate family circle, and family conflict exerts an important influence on their experience of stress. Caban & Walker (2008) found that women reported more symptoms of depression than men, and related it to the lack of perceived support from their immediate family circle. Spanish-speaking men reported less symptoms of depression and high levels of social support from their spouses. Women frequently report feeling overwhelmed by the duties of working at home and outside the home simultaneously.

Younger women are expected to put their personal needs aside to attend to those of their families. Women older than 55 instead feel less demanded and report less stress (Caban & Walker, 2008). Women are also more vulnerable to family conflict and empty nests, complaining that their children don't care for them as they would if they were in their country of origin (Olvera, Stewart, Galindo, & Stephens, 2007). Women also tend to value emotional support from friends that alleviate the stress of family duties, more than the instrumental support (Cherrington et al., 2008; Olvera et al., 2007). Sometimes, family is a source of stress by the role reversal that takes place when children tell adults what to eat and when to check their blood sugar (Hatcher, 2007). Intervention strategies that incorporate social support are acceptable to all cohorts but may have more impact for older groups who see their circle of peers diminishing over time.

Seeking professional help: to address stressful personal or family situations has limited appeal (Alvidrez, 1999; Rojas-Vilches, Negy & Reig-Ferrer, 2011). To have a "mental problem" is associated with embarrassment and shame (Cabassa, Hansen, Palinkas, & Ell 2008). Latinos show apprehension about taking antidepressant medication. Professional counseling and/or cognitive therapies may be well

received and implemented if there is access to those services, and may be combined with prayer. Women are more likely to participate in activities in which "you can talk to someone." Men however, tend to keep feelings to themselves. Professional counseling becomes a good strategy to implement and may be more acceptable to younger cohorts since they have grown older in times when psychological counseling is more widely available and applied (Cabassa et al., 2008). These services however, remain unattainable for undocumented Latino immigrants.

Physical activity: such as walking and dancing are welcomed but running, swimming or bike riding are considered too "Anglo", and have limited acceptance. However, activities that involve their social networks and the family are well accepted (Vincent, Clark, Zimmer, & Sanchez, 2006). Formal exercise is more likely accepted among those with higher education (Marquez et al., 2004). This strategy needs to consider the cultural factors to make it appealing. Strenuous physical activity may be welcomed by those with high education, and by women. Low impact activity involving the family and friends and in familiar surrounds has more receptivity (Marquez et al., 2004).

Although not much attention is given in the literature to differential experiences by age cohorts among Latinos, two qualitative studies reported 55 years as a time of transition to a stage of less demands in family life for women, and hence women older than 55 reported less stress (Caban & Walker, 2006; Hatcher & Whittemore, 2007). Future studies should further evaluate this finding.

6. **Stress Management for Older Adults**

There is a paucity of data on self-management interventions incorporating quality of life or psychological components for older adults. A meta-analysis on chronic disease self- management in older adults by Chodosh et al. (2005), made almost no reference to the psychological components of self-management programs. This exemplifies how this area of health is overlooked in favor of a more

instrumental approach to self-management education. A review of the literature on diabetes self-care interventions for older African American and Latino adults by Sarkisian and colleagues (2003) evaluated 12 studies and found that four of eight randomized trials evaluated the effects of the interventions on quality of life, and three of them did not show changes in those scores post-intervention. They identified the following as characteristics of successful interventions: poor baseline glycemic levels; tailored to the culture or age of the participants; use of group counseling or support, supplemented in several cases by one-on-one sessions with nutritionist or diabetes educator; involvement of spouses or children in the education process; and aimed at changing behavior rather than only educating patients, thus giving the individual the tools to solve his/her own problems. Only one of the six programs designed specifically for older adults maintained the positive outcomes beyond the intervention (Sarkisian et al., 2003).

Finally, it is important to consider the coping strategies used by community dwelling older adults in informal settings. As social networks diminish over time for older adults, prayer becomes the most common form of coping (Koenig, Smiley, & Gonzalez, 1988; Martin et al., 2001). Prayer has been associated with reductions in depression and improvements in quality of life in hospitalized patients (Ai, Dunkle, Peterson, & Bolling, 1998) and religiosity shows reductions in markers of inflammation (Koenig et al., 1997). It is likely that religiosity, prayer and other forms of informal coping consistently and significantly influence self-care behaviors and health outcomes in community settings.

7. **Physical Activity**

    a. **Physiological effects**

The American College of Sports Medicine defines physical activity as bodily movement produced by skeletal muscle contraction that increases energy expenditure. Exercise is the practice of "physical activity in a planned, structured and repetitive manner to improve or maintain one or more

components of physical fitness" (American College of Sports Medicine, 2009). Aging brings about physiological changes and alterations in body composition that lead to reduced functional capacity and reductions in amount and intensity of physical activity (Janssen & Ross, 2005; Kay & Fiatarone Singh, 2006; Racette, Evans, Weiss, Hagberg, & Holloszy, 2006; Singh, 2004). Aging is also associated with increased risk for chronic diseases (Kay & Fiatarone Singh, 2006; Singh, 2004) but physical activity significantly decreases that risk (Blair & Wei, 2000; Fitzgerald, Barlow, Kampert, Morrow, Jackson, & Blair, 2004; Katzmarzyk & Craig, 2002). There is substantial evidence that regular physical activity increases life expectancy by preserving functional capacity, reducing development of chronic disease, and slowing down biological changes related to age. There is also substantial evidence that older adults are able to engage in aerobic and resistance exercise and experience physiological adaptations similar to those of younger individuals (Seals, Taylor, Ng, & Esler, 1994). For example, the response to sub-maximal aerobic exercise maintains control of blood pressure, blood homeostasis and oxygenation, organ perfusion and dissipation of heat; acute response to resistance exercise preserves cardiovascular and neuromuscular adjustments (Seals et al., 1994). Long-term adaptation to exercise training is also similar to that of younger adults, with relative increases in VO2 max (Huang, Gibson, Tran, & Osness, 2005), exercise tolerance, endurance (Vincent, Braith, Feldman, Magyari, Cutler, Persian et al., 2002), muscle strength and size (Roth, Ivey, Martel, Lemmer, Hurlbut, Siegel, et al., 2001), and reduction in accumulation of central adiposity (Holloszy & Kohrt, 1995). Long-term aerobic training increases skeletal muscle adaptations and cardiovascular reserve that allows more exercise with less fatigue and cardiovascular stress. Older adults however, show reduction in exercise tolerance and increased risk of heat/cold injury (Kemney & Munce, 2003). Resistance exercise slows down the loss of strength, muscle mass and bone mass. In fact, older adults can substantially increase strength (Fielding et al., 2002), muscle power (Izquierdo, Häkkinen Ibañez, Garrues, Antón, Zúñiga, et al., 2001), muscle quality, and fat free mass with regular practice of resistance exercise training (American College of Sports Medicine, 2009).

b. **<u>Psychological well-being</u>**

Significant evidence associates physical activity with psychological well-being. Aerobic exercise and physical fitness show decreased risk of depression and anxiety, reduced risk of dementia and cognitive impairment, and improvement in quality of life (Blumenthal, Babyak, Moore, Craighead, Herman, Khatri, et al., 1999; Dunn, Blair, Marcus, Carpenter, & Jaret, 2001; Mather et al., 2002). One of the pathways associated with these effects include reduction of inflammatory adipokines and cortisol implicated in hypoccampal atrophy, impairment of cognitive and affective function and visceral adiposity (Lyons, Yang, Eliez, Reiss, & Schatzberg, 2004; Porter & Landfield, 1998; Whitmer, Gunderson, Quesenberry, Zhou, & Yaffe, 2007; Yaffe et al., 2007). Studies suggest that the effect of exercise on psychological well-being may be mediated by self-concept, self-esteem, and self- efficacy (Dunn, Blair, Marcus, Carpenter, & Jaret, 2001; Folkins & Sime, 1981). Moderate to high intensity resistance exercise training also shows improvements in anxiety, clinical depression, and quality of life (Singh, Clemens & Fiatarone, 1997; Tsutsumi et al., 1998).

Research during the last decades has found that chronic stress impacts health through accelerated cellular aging (Epel, Blackburn, Lin, Dhabhar, Adler, 2004). This cellular aging is marked by telomere shortening that has been associated with heart disease, diabetes and early mortality. Recent studies that consider the effects of stress and aging have found a positive effect of exercise on telomere length. Endurance trained athletes show longer telomeres compared to sedentary controls. Studies found that the practice of vigorous aerobic exercise preserved telomere length (Du, Prescott, Kraft, Han, Giovannucci, et al., 2012; LaRocca,Seals, & Pierce, 2010). Telomere length is also associated with maximal aerobic exercise capacity (LaRocca et al., 2010), but not with sitting and sedentary behavior in women (Du et al., 2012).

c. **Physical activity and diabetes**

Physical activity is an essential element of diabetes self- management, along with diet and medication (ADA, 2015). The ADA's current guidelines recommend 150 minutes of aerobic exercise per week, and resistance exercise three times per week (ADA, 2015).

Several randomized trials and meta-analyses find that exercise has significant effects on insulin resistance, fasting glucose levels, and A1C. They also find differences in the effects of aerobic, resistance, and combination exercise on diabetes markers (Hansen et al., 2009; Mendonca, Pereira, Neves de Oliveira, Resende, Ferreira, et al., 2011; Sigal et al., 2007; Umpierre et al., 2011). In their randomized controlled trial, Sigal et al. (2007) compared aerobic training, resistance training and their combination in a group of 251 adults with type 2 diabetes. A sedentary control group was also included. The study evaluated changes in A1C, body composition, plasma lipids, and blood pressure at six months. No significant changes were observed on intervention groups compared to control in blood pressure, lipids and body composition. However, significant changes were observed in A1C in all intervention groups. The combination of aerobic and resistance exercise demonstrated superior effect on A1C than either one of them alone (Sigal, et al., 2007).

Hansen et al. (2009) evaluated the impact of exercise intensity on the benefits of exercise training on A1C over six months. Fifty obese participants with type 2 diabetes were assigned to either a low intensity or a high intensity exercise group. Both groups were matched for energy expenditure. Low intensity sessions were 55 minutes at heart rate corresponding to 50% of baseline peak VO2 (105 ± 3 beats/min), and high intensity were 40 minutes at heart rate at 75% of baseline peak VO2 (118 ± 3 beats/min). After six months of training, there were clinically significant reductions in A1C, increase in muscle mass and muscle oxidative capacity on both groups. Low-to-moderate intensity showed to be as

effective as moderate-to-high intensity exercise when longer duration compensated for the lower intensity (Hansen et al., 2009).

Mendonca et al. (2011) also found that different exercise modalities affect several biomedical markers in patients with type 2 diabetes including fasting glucose, A1C, lipids, insulin resistance index, and C-reactive protein. Aerobic, resistance and a combination of both were compared to a control group doing light stretching exercises, three times per week for 12 weeks. Results did not show significant differences between groups except for an elevation in insulin receptor substrate (IRS)-1 in the resistance and combined training groups, indicating an increased effect on insulin-related glucose uptake by the muscle cells (Dresner et al., 1999; Griffin et al., 1999).

Finally, a meta-analysis by Umpierre et al. (2011) assessed the effect of physical activity advice versus structured exercise training on levels of A1C. They evaluated 47 randomized controlled trials of which 23 were of structured exercise training and 24 were of physical activity advice. In general and compared to controls, structured exercise training was associated with A1C reductions of 0.67%; aerobic exercise reduced an average of 0.73%; resistance training, 0.57%; and their combination, 0.51%. Exercise of more than 150 min of duration per week was associated with reductions of 0.89% compared to controls; exercise of less than 150 min/week, were associated with reductions of 0.36%. In general, physical activity advice was not associated with reductions in A1C unless it was combined with dietary advice, in which case it would show a reduction of 0.58% compared to controls.

In conclusion, physical activity is strongly associated with A1C reduction even at low levels of intensity as demonstrated by Hansen et al. (2009) and Mendonca et al. (2011). This finding is of importance for the majority of patients who show low adherence to high intensity exercise, including those with risk for complications (hypoglycemia, etc). Emphasizing these benefits should be part of the

recommendation for all patients with type 2 diabetes. From this information it's also inferred that a truly effective control group should not be implemented with low intensity exercise, but with physical activity advice alone.

8. <u>Tai Chi</u>

The ancient Chinese martial art of Tai Chi is widely practiced in Asia. In Tai Chi, the individual can reach a calm, steady mind and a relaxed body. Tai Chi emphasizes gentle, slow, circular movements with shifts in balance, maintaining the center of gravity while the body rotates in smooth motion. Simultaneously, the individual maintains relaxation and meditative attention with diaphragmatic breathing (Lam, 2001). There are several styles of Tai Chi practice such as Yang, Wu and Sun, and short and long forms. The long form consists of 108 movements; Yang short form can be of 37 or 24 moves or adaptations of 12 movements or less (Lee, Lee, Kim, & Ernst, 2010; Wang et al., 2010; Yeh, Wang, Wayne, & Phillips, 2008). I used the Yang 24 for this study.

a. <u>Evidence of physiological effects</u>

Tai Chi is considered low impact, moderate cardiovascular exercise because demands 55 to 67% of heart rate reserve, and can benefit balance and cardiovascular and respiratory function in older adults (Bronas, 2009). A review of the literature evaluating 47 studies on the effects of Tai Chi on clinical conditions finds significant improvement in balance, flexibility and strength in elderly community dwellers; improved cardiovascular fitness, reduced risk of falls and improved gait velocity (Wang, Collet, & Lau, 2004). In arthritis, Tai Chi shows improved symptoms, self-efficacy and quality of life. Tai chi enhances cardio-respiratory function, producing higher VO2 scores and work rate; reduces mean, systolic and diastolic blood pressure in hypertensives and in patients recovering from myocardial infarction. Studies evaluating the effects of Tai chi on endocrine and immunity markers found significantly higher number of circulating T lymphocytes. Although studies show contradictory findings

regarding the effects of Tai Chi on A1C levels, insulin resistance and fasting glucose (Bronas, 2009), two RCTs have found reduction in body fat and central adiposity as well as improvement in insulin resistance (Tsang, Orr, Lam, Comino, & Singh., 2008) and blood glucose levels (Yeh et al., 2007).

b. Evidence of psychological effects

The majority of the published studies on Tai Chi evaluate physiological as their primary outcomes, with only a handful reporting on psychosocial or mental health variables as their primary outcomes. Psychological outcomes evaluated were quality of life, depression, mood, self-esteem, perceived stress, satisfaction with life, and state and trait anxiety. Descriptive studies suggest that Tai Chi practice favors improvement in mood, anxiety, vitality and social functioning compared to sedentarism (Bond, Lyle, Tappe, Seehafer, & D'Zurila, 2002; Chen, Snyder, & Kirchbaum, 2001; Ho, Wen-Min, Lien, Ma, Kuo, Chu, et al., 2007; Jin, 1989, 1992). The studies by Jin find that Tai Chi induces physiological changes that may be responsible for the improvements in psychosocial functioning: reduction in salivary cortisol and increased excretion of noradrenaline, increased heart rate, and lower blood pressure are similar to those found in other forms of physical activity and meditation (Jin, 1989, 1992).

RCTs assessing psychological markers found improvement in depression and psychological distress, positive well-being, life satisfaction, and perception of health in older adults (Lee, Lee, & Woo, 2007; Lee, Lee, & Woo, 2009; Li, Duncan, Duncan, McAuley, Chaumeton & Harmer, 2001; Li, Harmer, Chaumeton, Duncan, & Duncan, 2002; Taylor-Piliae, Haskell, Waters, & Froelicher, 2006). Patients with post-traumatic stress disorder found relief to their mental health conditions with the use of Tai Chi and Qi Gong combined with pharmacotherapy and psychotherapy (Grodin, Piwoarczyk, Fulker & Saper, 2008). In general, results support an effect of Tai Chi on psychological health by reducing anxiety, depression, perceived stress, and improved self-esteem, vitality and social functioning. The

majority of the studies have been implemented for the older adult population, and participants have been mostly women (72.3%). A meta-analysis by Wang (2010) reports on the results of 21 studies assessing the impact of Tai Chi on psychological well-being, particularly on stress reduction, anxiety, depression, mood and self-esteem. Results for four RCTs and four non-randomized studies assessing effects on stress in persons with HIV, elderly with osteoarthritis, elderly with cardiovascular disease risk factors and healthy participants, showed significant improvement in psychological distress and stress management (ES=0.66). Five RCTs and nine non-randomized studies evaluated anxiety reduction with Tai Chi and found significant reduction in persons with fibromyalgia, osteoarthritis, cardiovascular risk factors, or healthy adults (ES=0.66). For depression, nine RCTs and four non-randomized studies examined the impact of Tai Chi on depression in patients with fibromyalgia, osteoarthritis, rheumatoid arthritis, cardiovascular risk factors, depression disorders, sedentary obese women and healthy adults. Tai Chi practice significantly reduced depression compared to controls (ES=0.56). Two RCTs and four non-randomized studies assessed impact on mood in individuals with HIV, cardiovascular risk factors, and healthy adults, and found improved mood compared to controls with an effect size of 0.45. Only three RCTs and one non-randomized study assessed Tai Chi on self-esteem with insufficient data for a meta-analysis.

In general, there is wide variety in the quality of the studies and in implementation methods, including intensity and length of intervention making it difficult to generalize results. But growing evidence supports the benefits of Tai Chi for physical and mental health. The literature is unanimous in recommending further exploration of these positive findings in psychological as well as physical health (Lee, Jun, Lim, & Lim, 2015; Wang et al., 2010).

II. Theoretical Framework

A. <u>Conceptual Model of Stress Reduction for Self-management of Diabetes</u>

Our conceptual model is a modification of the **bio-psycho-social model** proposed by Peyrot, McMurry, & Kruger (1999) (see Figure 1). The behavioral model in the management of diabetes focuses on adherence to regimen, controlling peak levels of blood glucose by reducing caloric intake, controlling foods of high glycemic index, doing exercise, and taking medication according to plan. The psycho-physiologic model states that psychosocial stress affects glucose levels in response to stress hormones regardless of regimen adherence, and also affects the ability to comply with regular behavioral routines (Peyrot, McMurry & Kruger, 1999). Peyrot's model recognizes chronic, transient and momentary processes in which stress and coping operate and co-operate to affect biological integrity and adherence to self-management. Stressors exert direct effects on the physiology and also indirect effects by influencing psychological variables and behaviors. Education modulates stress effects through awareness, cognition and enhancing self-efficacy (empowerment) (Ensel & Lin, 1991; Peña-Purcell, 2011). Social support modulates the emotional response and facilitates the engagement in healthy behaviors (diet, exercise, etc.) (Hatcher & Whittemore, 2007). Stress management modulates the physiological, behavioral and psychological variables, and complements the impact of cognitive interventions, to further reduce effects of stress on affect, behavior and physiology.

In the focus groups conducted among Hispanic/Latino older adults in Chicago prior to this quantitative evaluation, participants asserted that psychological stress affected their glucose levels, and diabetes was an important stressor, particularly in the absence of appropriate social or family support. Physical activity was identified as a common strategy for stress reduction and for diabetes self-management, but its practice was strongly influenced by the level of social support. Perceived social

support varied by gender. Men had high levels of support from their wives, but women reported less support from their spouses and children. When asked about their ideal conditions for the practice of physical activity including Tai Chi, they advocated for having group classes, with verbal guidance and support in their own language from an instructor. Group classes and personal instruction were considered elements that provided social support and enhanced their exercise self-efficacy.

The conceptual model presented here is designed to describe the main associations related to stress reduction and diabetes self-management identified in the literature, and additionally adapts Peyrot, McMurry and Kruger's (1999) psycho-physiological model to incorporate the role of social support and self-efficacy. The current dissertation study was designed to evaluate Tai Chi as a potential physical activity intervention to influence diabetes health outcomes. The study was not designed to address the relationships represented by the model.
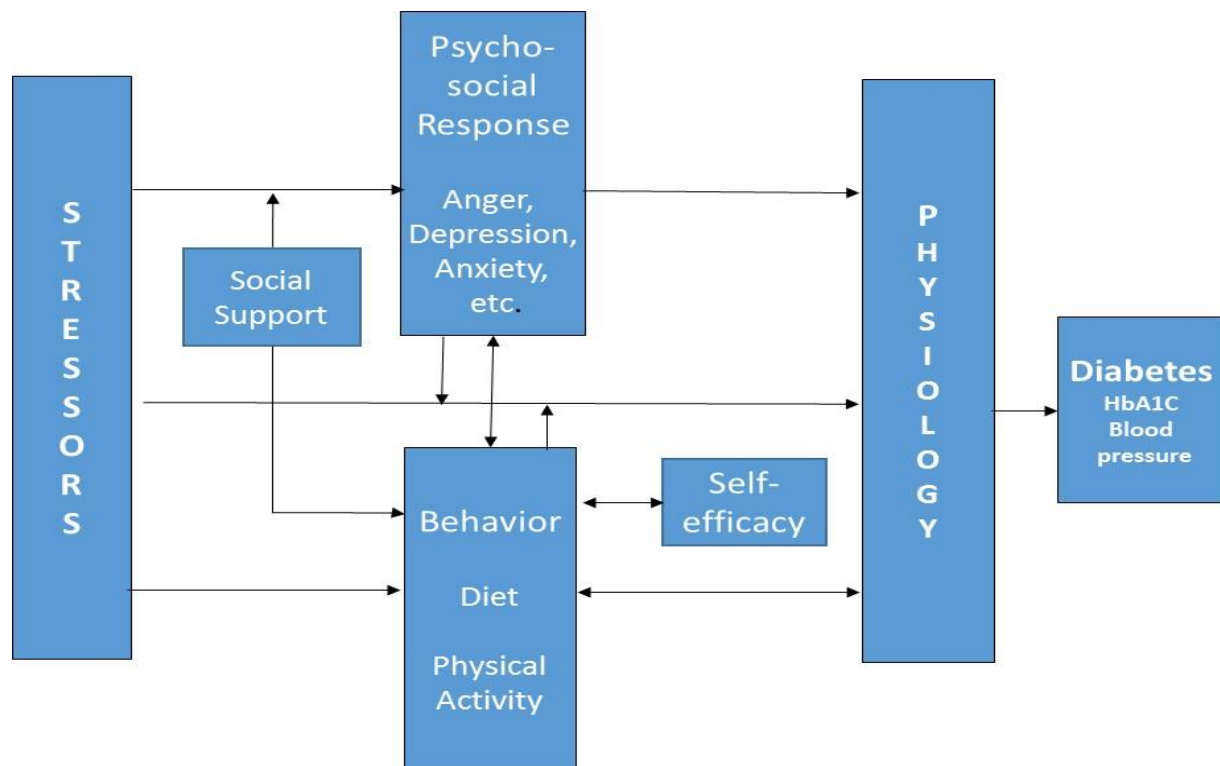
Adapted from Peyrot, McMurry, and Kruger (1999).

Figure 1. Conceptual Model of Stress and Diabetes

1. **Stressors**

I divide the stressors for Latinos into three categories: societal, ethno-cultural and diabetes-specific. Stressors independently influence biological systems generating changes in glycemia, and also initiate internal processes of appraisal to engage in behavioral response. The relationships between stressors and physiological systems have been extensively discussed previously.

2. **Psycho-social Response**

Peyrot, McMurry, and Kruger (1999) find a positive association between stable emotional types and glycemic control. Among Latinos, cultural beliefs and individual attitudes or traits such as pessimism, anxiety, etc., influence their response to stressors. Common psychosocial responses are characterized by venting, denial and avoidance when facing a powerful stressor (e.g. denial of diagnosis of diabetes, venting in the presence of multiple demands, etc.) (Hatcher & Whittmore, 2007). Latinos tend to rate their health status as poor, or assume fatalistic views ("I have to die someday…") (Hatcher& Whittmore, 2007) that may enhance the perceived severity of the threat, or they may deny the importance of the problem and delay attention to it; offer resistance to biomedical authority insensitive to the patient's perspective (Schoenberg, Drew, Palo-Stoller, & Kart, 2005); or a "strong" disposition that allows them to handle stress (Hatcher & Whittmore, 2007). Our focus groups findings suggest that fatalism and pessimism together with withdrawal, denial, anger are common responses to stressors.

3. **Behaviors**

In diabetes, self-care behaviors are adaptive responses to the disease and to stress (Wenzel, Glanz, & Lerman, 2002). Specific self-care behaviors in this model are diet, exercise, foot care, glucose self-monitoring, and medication adherence. Adoption or disruption of any of these behaviors impacts glycemic control. The most important correlate of successful self-care outcomes in Latinos is self-efficacy, which in turn, is significantly influenced by health education (Peña- Purcell, 2011). Self-

efficacy is considered by Ensel and Lin (1991), an important psychological resource that influences an individual's reaction to stressors, or buffers the impact of the stressor on subsequent illness.

Peyrot, McMurry and Kruger (1999) find that being married and having education facilitate glycemic control. Social support and education have a moderating role in addressing stressors among Latinos according to qualitative reports (Hatcher & Whittmore, 2007). *Social support* includes social networks, and meaningful relationships. Among Latinos, *familismo* represents a source of emotional and instrumental support defined by feelings of loyalty, strong connections and centrality of family. Social support is perceived from the nuclear and extended family, close friends, and advocates for the patient such as a community health worker. These ties strongly influence self-efficacy, provide emotional support, facilitate problem management, and facilitate sustaining intention and behavior under difficult circumstances. Among Latinos, social support is an important element for the initiation and sustainability of self-care behaviors (Hatcher, 2007 & Whittmore; Wen, Shepherd & Parchman, 2004). Social support buffers the impact of stress by enhancing self-efficacy, the implementation of positive coping strategies, and adaptation. Our preliminary evaluation of Latino older adults in Chicago finds that social support strongly influences the engagement in physical activity, diabetes self-care management and stress reduction practices.

Our findings also lend support to previous reports that among Latinas, *familismo* and gender roles may influence negatively their self-efficacy and sense of control. For Latino men, spousal support positively influences self-efficacy, sense of control and behavioral change (Caban et al., 2008).

Other resources that exert direct effects on well-being include individual behaviors and health practices such as diet, exercise, and stress management (Ensel & Lin, 1991). Among Latinos assessed in our preliminary evaluation, stress management is frequently operationalized in the use of prayer,

exercise, listening to sound, gardening and other activities to regain emotional balance and adapt to the stressful situation (Hatcher & Whittmore, 2007). In this conceptual model, Tai Chi mobilizes resources that help to prevent, lessen or recover from the impact of the stressors on physical and emotional well-being (Ensel & Lin, 1991).

B. <u>Research Questions</u>

Research has found that Tai Chi can successfully improve insulin resistance (Tsang et al., 2008) and effectively reduce blood glucose levels (Yeh et al., 2007). Therefore, practicing Tai Chi regularly may be a beneficial secondary prevention technique for diabetes self-management and stress reduction; and, may also impact tertiary prevention by decreasing the risk of developing co-morbidities such as cardiovascular disease. There is limited research to date observing the use of complementary medicine for self-management of diabetes related stress. I propose to use Tai Chi compared to health information to improve levels of A1C and stress.

The aims of this study are:

1. To determine the feasibility of implementing Tai Chi as a stress management technique among Hispanic patients with type 2 diabetes;

2. To assess the impact of Tai Chi as a stress management technique vs. health education on:

   a) glycemic levels;

   b) blood pressure levels; and

   c) levels of stress.

The hypotheses of this study are that:

1. It is feasible to implement Tai Chi as an alternative stress management technique for Hispanic patients with type 2 diabetes.

2. When compared to those receiving health education, patients assigned to the Tai Chi stress management program will have a:

   a) significant decrease in A1C levels;

   b) significant decrease in blood pressure; and

   c) significant decrease in stress scores.

III. Methods

A. <u>Design</u>

This was a randomized controlled trial (RCT) comparing a group practicing Tai Chi (intervention) versus a delayed intervention group receiving health education (control). At the end of the treatment phase, there was a control group cross-over to receive the intervention.

This design is a 2 (Tai Chi vs. health education) X 2 (time—baseline & 12-weeks) repeated measures design (see Figure 2). After randomization (RA), observations/assessments (O) for both the treatment and control groups took place at baseline, and at the end of the first 12-week intervention (X_1 for the treatment group; X_2 for the control group). After this second observation, the control group crossed over and received the Tai Chi treatment (X_3) and a third assessment/observation was conducted at post-test.

$$O \quad X_1 \quad O$$

$$RA$$

$$O \quad X_2 \quad O \quad X_3 \quad O$$
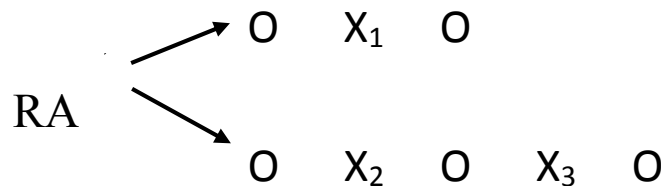
Figure 2. Repeated Measures Design

B. <u>Target Population and Settings</u>

The target population consisted of previously diagnosed Hispanic patients with type 2 diabetes who resided in the South Chicago, East Side and Hegewisch communities of Chicago (N=72,030). The

chosen communities are demographically similar neighborhoods with a significant Hispanic population. In South Chicago, a community of about 40,000 people, 29.8% of households are below the poverty level, 26.6% of residents do not have a high school diploma, unemployment is at 19.7%, and per capita income is only $16,500 (CDPH, 2015).

1. **Eligibility Criteria**

This study compared health advice to the practice of Tai Chi. Enrollment of participants was based on the following inclusion criteria:

- Men and women self-identified as Hispanic or Latino;

- 50 years to 80 years old;

- Diagnosed with type 2 diabetes;

- Able to exercise.

Exclusion of participants will be based on the following criteria:

- Prior formal introduction to relaxation techniques, yoga, Tai Chi or meditation;

- Practicing regular exercise;

- Self-reported substance abuse;

- Serious co-morbid condition (e.g. cancer, HIV), or with complications from diabetes that could worsen with the practice of low intensity exercise (foot ulcers, retinopathy, kidney disease);

- Difficulty standing on their two feet, or need for assistive devices;

- Person seems disoriented, or confused at interview;

- Unwillingness to sign informed consent or to be randomized;

- Will travel outside of Chicago for more than two weeks within the next four months (to ensure sufficient participation in the program).

2. Recruitment and Enrollment

Participants were recruited via: (1) flyers and posters distributed at the clinic, senior centers, YMCA, community centers and other venues in the community (see Appendix A); (2) addressing congregations at churches during religious services on Sundays (see Appendix B); (3) direct mailings from Chicago Family Health Center inviting participants to the study (see Appendix C); (4) Participants from phase 1 (focus groups) were invited to participate in the trial. Letters and flyers displayed the phone number to contact researchers. Chicago Family Health Center's providers were informed about the study at medical staff meetings and invited to refer patients to the study if they fulfilled eligibility criteria. Recruitment was continuous until enrollment had reached sufficient number of participants for randomization into two groups.

One hundred and fifty six community residents were screened from among those responding to flyers and announcements at churches and community organizations. One hundred and seven were excluded because were considered ineligible by the established criteria or declined participation (see Figure 3).

Recruitment efforts and enrollment started in the Fall of 2012 and continued until the Summer of 2013. Two rounds of intervention took place: one in the Spring with 22 participants and the other in the Summer with 19.

C. Eligibility Screening and Informed Consent

Screening took place in two stages: the initial screening at first contact with the potential participant assessed inclusion/exclusion criteria (diabetes diagnosis, ethnicity, sex, intention to travel, co-morbid conditions) and collected contact information (name, phone number) (see Appendix D). This first screening was conducted by the CHW or the PI, either over the phone or in person. Those who were

considered eligible were invited to an in-person interview for the second screening conducted by the PI. In this meeting, I used a modification of the EASY tool, a questionnaire that assesses risk of engaging in physical activity and helps in decision making (Resnick et al., 2008b) (see Appendix E). Growing evidence suggests that screening for moderate level of physical activity is not needed, and there is greater risk in remaining sedentary. The American Heart Association and the American College of Cardiology have reached consensus on appropriate screening guidelines for participation in physical activity (Gibbons, Balady, Beasley, Bricker, Duvernoy, et al., 1997; U.S. Preventive Services Task Force, 2004). The stress test is no longer a routine recommendation for those who want to start practicing physical activity, and asymptomatic sedentary older adults can safely initiate physical activity of moderate intensity even in the absence of a recent medical evaluation (Cress, Buchher, Prohaska, Rimmer, & Brown, Macera, et al,, 2005; Pescatello, DiPietro, Largo, Ostfeld, & Nadel, 1994). Participants in the study Stress Reduction with Tai Chi for Elderly Hispanics were administered an adaptation of the Exercise Assessment and Screening for You (EASY), developed and successfully used by Barbara Resnick, PhD, for risk assessment during the screening (Resnick et al., 2008a; Resnick et al., 2008b). I used modifications of the EASY recommendations to accommodate conditions related to diabetes. These EASY questions and the recommendations, followed by our corresponding procedures are described in Appendix E.

Participants received informed consent right after completing the second screening. Biomedical informed consent was used; no HIPAA authorization was required because all data collected was self-reported and I did not request access to medical records. I provided informed consent either in English or Spanish according to the participant's preference. I read out loud the consent form to the individual or group, and asked them questions to ensure they understood. Participants were encouraged to ask any questions, and responses were given in both English and Spanish. Those who signed up received a copy to take home (see Appendix F).

D. __Randomization__

Following screenings and consent, and after collecting a sufficient number (N>20), participants were placed into either control or intervention groups by computerized randomization. In March 2013, randomization was conducted on the first 40 participants: 20 assigned to the Tai Chi group and 20 to the control. Randomization at the individual level was conducted using the Randomizer website. At the initial screening the participant was assigned a temporary screening number; upon enrollment and after consent each participant was given an ID number; the randomization program then indicated group assignment for each ID number.

At the first session, participants were informed of their assignments to either treatment of control groups. Upon assignment and after classes had started, two members of the control group moved to the intervention group. One of them found out that work commitments in the Summer were not going to allow her to participate in the delayed intervention. The other participant misunderstood his assignment.

Recruitment efforts continued while the first group received Tai Chi instruction. At the end of the three-month intervention when the control group was due to start its Tai Chi classes, there were insufficient numbers recruited to form two groups. Therefore due to practical constraints the new recruits (N=9) were added to the second intervention group. A total of 49 participants were enrolled and signed informed consent. Forty were randomized, and due to the cross-over, 41 received the Tai Chi classes (see Figures 3 and 4).
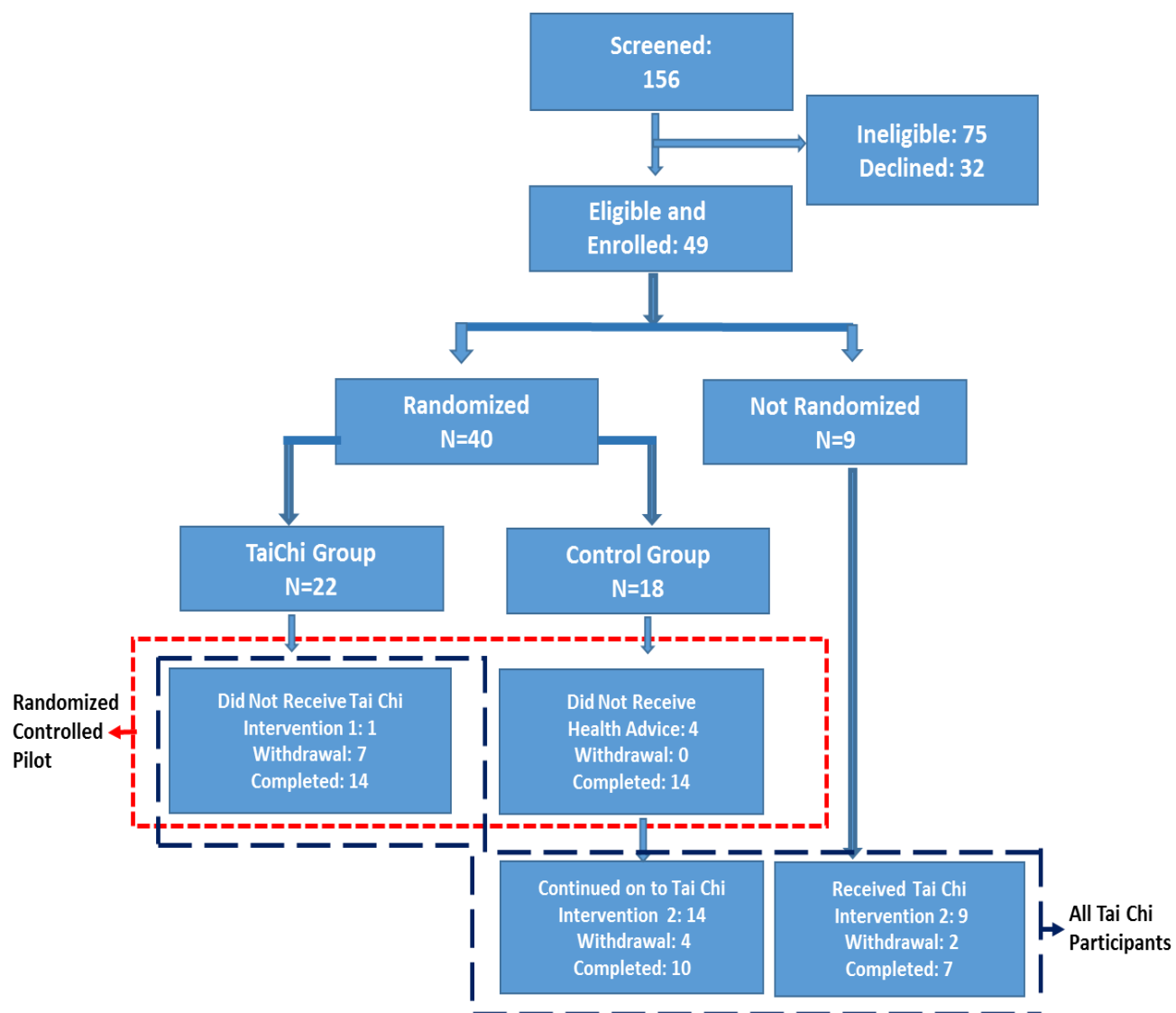
Figure 3. CONSORT Table

Whole Sample
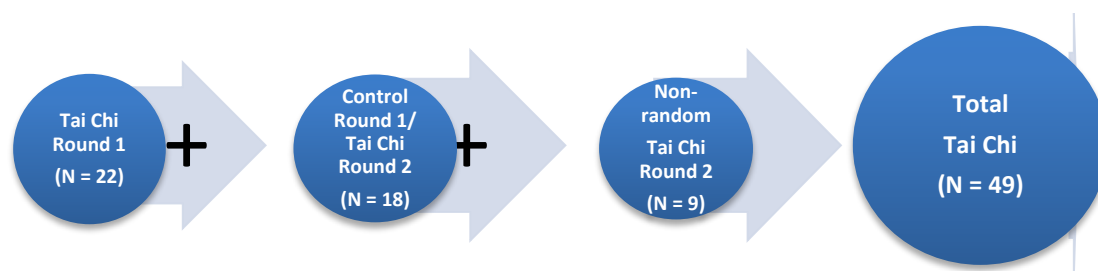
Randomized Controlled Pilot
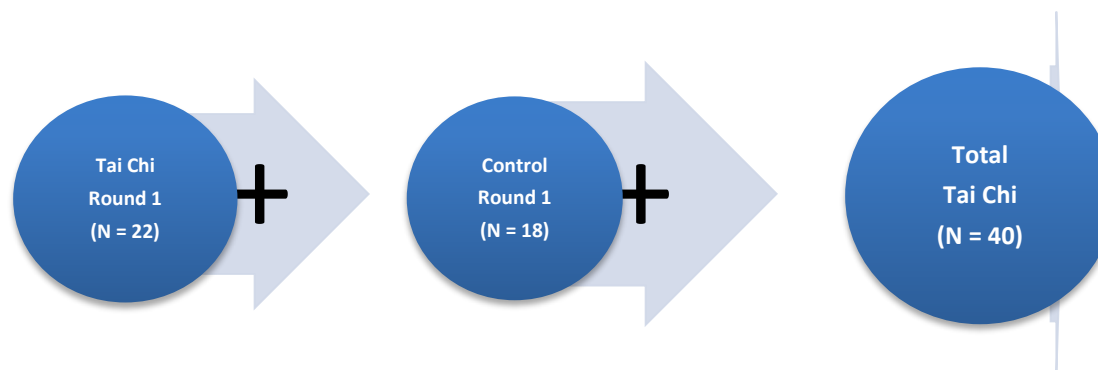
All Tai Chi Participants
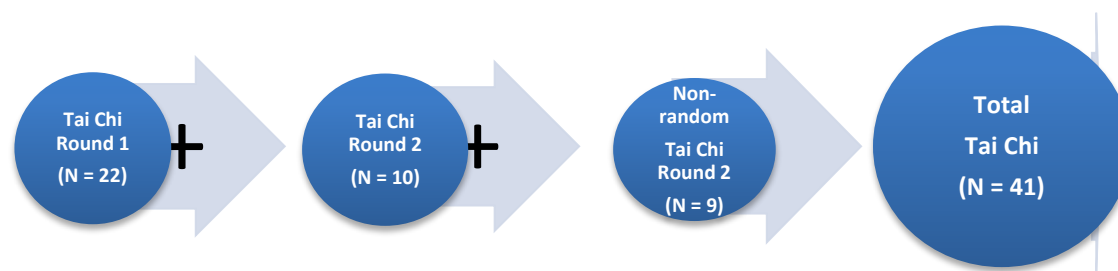
Figure 4. Study Samples

For the purpose of analysis, the group is divided into two cohorts. Those in the "Randomized Controlled Pilot" are the first 40 participants who were enrolled and subsequently randomized. "All the Tai Chi Participants" are those (N=41) who received the Tai Chi intervention, either in the first round (randomized) or the second round (non-randomized). Results are presented separately for the two cohorts (see Figures 3 and 4).

E. <u>Intervention</u>

The intervention was conducted from March through August of 2013. There were two rounds of Tai Chi classes. The first round was the comparison between the Tai Chi and the delayed intervention control group. The second round was the intervention for the control group, including the nine newly enrolled participants.
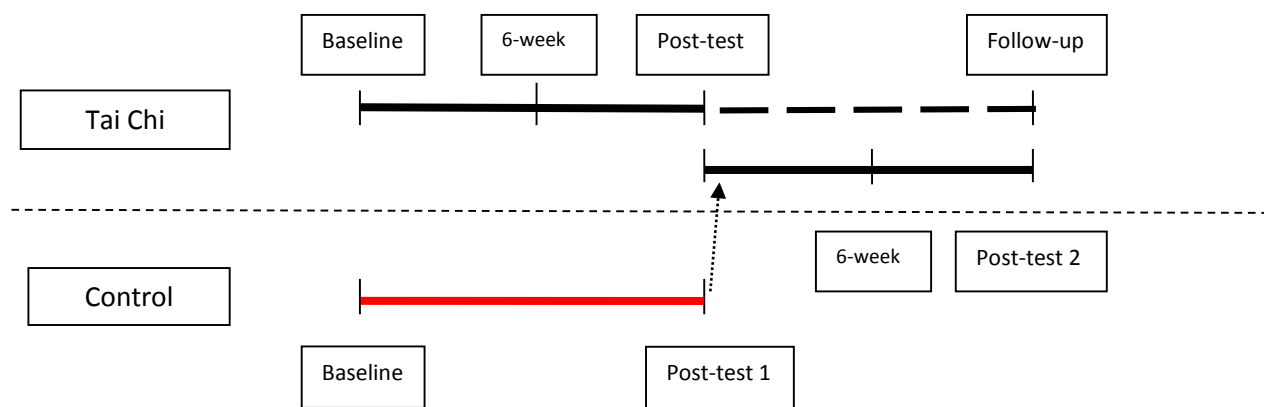
Figure 5. Participant Flowchart

1. <u>Treatment Group–Tai Chi</u>

During the Spring of 2013 the intervention group received instruction in the short form Yang style Tai Chi, in two 1-hour long sessions every week for 12 weeks. A certified bi-lingual Tai Chi instructor led the intervention group. Contact time included a maximum of 23 hours of Tai Chi instruction plus two sessions for baseline and post-test assessments, for a total of 25 contact hours for each participant. The location chosen for the intervention sessions (the solarium at Chicago Family Health Center facilities) had easy access by the participants and offered sufficient space to comfortably conduct the activities.

TABLE I
TAI CHI INTERVENTION

Week 1	Introduction to Tai Chi:
	○ Orientation to class, instructors and peers
	○ Discussion of essential principles of Tai Chi
	○ Demonstration of Tai Chi movements
	   • Warm up
	   • Breathing exercises
	   • Cool down
		Week 7	○ Half-way mark: review progress, reinforce goals;
			○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts.
			○ Rehearse exercise behavior with addition of 3 new fundamental moves.

Week 2	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 fundamental moves.	Week 8	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 new fundamental moves. ○ Combine moves into a "movement pattern"
Week 3	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 fundamental moves.	Week 9	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 new fundamental moves. ○ Combine moves into a "movement pattern
Week 4	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 new fundamental moves.	Week 10	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Combine moves into a "movement pattern"
Week 5	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 new fundamental moves	Week 11	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Combine moves into a "movement pattern"
Week 6	○ Review of exercise handouts and feedback: verbal encouragement, acknowledge individual efforts. ○ Rehearse exercise behavior with addition of 3 new fundamental moves.	Week 12	○ Review of exercise logs and feedback: verbal encouragement, acknowledge 3 individual efforts. ○ Combine moves into a "movement pattern" ○ Disseminate graphic documentation of basic forms (moves) ○ Closing

The intervention group received instruction on the postures and breathing exercises unique to the practice of Tai Chi. There are five different forms of Tai Chi and the sequence of postures chosen were the short version of Yang style (24 forms). It is the most popular and easy to learn and therefore easily incorporated into a daily routine (Lam, 2001). Each movement integrates the skills from the preceding movement and progresses in difficulty. The goal of the 12-week sessions was to teach the postures and incorporate them into the signature "movement patterns," while incorporating the mind-body principles central to Tai Chi and Qi Gong (Wayne & Kaptchuck, 2008). These principles include appreciating the body as a field of energy connected to the environment and the Universe; breathing as an intake of cosmic energy; imitating the movements that support and protect life in the animal kingdom; maintain an attitude of acceptance and gratitude toward life. These principles are inherent in the breathing,

concentration/focus of the mind on the body movements, imagery and visualization, interactions with instructor, fellow practitioners and the outside environment (Wayne & Kaptchuck, 2008). Every session included warm-up, breathing, and cool down exercises. Warm-up incorporated Qi Gong exercises to facilitate energy flow. Participants were expected and encouraged to continue to practice the exercises at home for at least five minutes daily. Biomedical, psychological and behavioral assessments were conducted at baseline and at the end of 12 weeks of Tai Chi. Assessment of acceptability and daily practice of Tai Chi were conducted at week six of intervention, and at post-test. Table 3 describes the content of the Tai Chi intervention sessions.

2. Control Group

The randomized control group attended a one-hour meeting with the PI every month for three months in which they received printed materials, and participated in discussions about nutrition, diabetes self-care, and physical activity (nutrition tips from the ADA, foot care, physical activity brochures). At the end of 12 weeks, the biomedical, psychological and behavioral assessments were conducted again, just as described for the treatment group. Then the control group initiated the intervention phase, in which they received instruction in the Tai Chi forms for another 12 weeks. At this time, only those who had completed post-test were included in the new intervention phase, together with 9 newly enrolled participants who had not been randomized. Post-test data collection for this delayed intervention group was conducted again at the end of 12 weeks of Tai Chi exercises.

3. Maximizing Participant Retention

Participant attrition was an important concern. Potential participants anticipating a departure from the community (i.e., a vacation or relocation during the period of instructional sessions), were excluded. I collected additional contact information (home phone, cell phone, participant's physical

address) in the event the participant moved. However, some people canceled or changed their phone numbers and could not be contacted in spite of multiple attempts, including sending letters by mail.

Participants were informed about the importance of participation and the benefits of adhering to the intervention. To encourage continued participation each participant received phone call reminders if they had missed a session the previous week.

The location, scheduled times, and choice of instructor followed the recommendations offered by participants in the preliminary focus groups. The local community clinic where the intervention took place was easily accessible by bus and offered free parking; the Instructor was bilingual; classes were scheduled at 5:30 pm to make it convenient for those who had regular jobs.

During intervention, participants had water and a healthy snack available at each session. Monetary incentives were provided to improve retention at baseline and post-intervention testing. Participants received $20 for answering each intake and post-test questionnaire, for a total of $40. At the end of the Tai Chi course, participants received a certificate and entered a raffle of two $10 gift cards. Those who had completed the mid-course short questionnaire were given an extra ticket for the raffle.

a. **Attrition**

A total of 15 participants (30.6%) did not receive the intervention or withdrew without completing the post-test. This group did not differ significantly from the completers in age ($p=0.75$); education ($p=0.23$); years since diabetes diagnosis ($p=0.95$); A1C ($p=0.097$), systolic blood pressure ($p=0.47$); diastolic blood pressure ($p=0.67$); perceived stress ($p=0.28$); diabetes distress ($p=0.99$);

intra/extra-familial stress (0.49); physical activity self-efficacy (p=0.62); social support (p=0.94); diet (p=0.29), or exercise (p=0.76). In the first cohort some enrolled participants had to wait months for the initiation of classes. In the interim, five of them withdrew or lost contact with the study. After initiating the intervention, seven participants withdrew in the Tai Chi group for health reasons or work conflicts. In the control group, 18 participants started the study, 14 completed post-test, but only 10 crossed over to the Tai Chi classes in the second round. Reasons for not continuing in the study were work conflicts and family demands. From the last nine recruits who joined the second round of classes, two withdrew due to transportation and health problems. In the second cohort a total of 41 participants initiated Tai Chi classes and 31 completed them (see Figure 3). Participants who discontinued participation were still included in the intent-to-treat analyses.

F. Assessment Measures and Procedures

The primary outcome of the study is level of A1C; secondary outcomes are: blood pressure and psychosocial stress. Diabetes self-care (including diet, physical activity, foot care, insulin use); physical activity self-efficacy, social support, medication adherence, healthy days, attendance to classes, adherence to Tai Chi practice at home, intention to continue exercise practice, and facilitators and barriers to exercise, were also measured and treated as covariates. Except for demographics assessed only at baseline, all other variables were assessed at baseline and at three months (see Appendix G and Appendix H). Acceptability of Tai Chi including barriers and facilitating factors to physical activity, adherence to Tai Chi home practice and intention to exercise were measured at week-6 of the interventions and at post-test (see Appendix I). Questions related to feasibility of implementation (e.g., acceptability, intention to continue practice) were included in the post-test questionnaire (see Figure 5).

1. **A1C**

Glycosylated hemoglobin (A1C) levels in blood were collected at baseline and at the end of the 12-week cycle following a standard protocol, applied uniformly to all participants. Participants cleansed the area and punctured the finger using disposable lancets. The researcher collected the drop of blood and placed the sample in the DCA 2000+ analyzer which provided the result in six minutes. Participants wrapped the punctured fingertip in a band aid. Results were recorded together with the questionnaires in the Intake and the Post-test Questionnaire Forms.

2. **Blood Pressure**

After resting for at least five minutes, brachial blood pressure was taken using an aneroid Lumiscope™ sphygmomanometer and a Littman™ stethoscope, with the participant sitting down and the arm resting comfortably on the table. Three measurements were taken and the average entered as the assessed value.

3. **Body Mass Index**

Participants were asked to take off their shoes, belts and heavy clothing. Weight was collected in pounds for all participants, using the same portable scale at both intake and post-test. Height was collected in inches once at intake using a tape measure attached to the wall. Confirmation with driver's license was secured when appropriate. Body mass index (BMI) was calculated using this formula:

$$BMI = \frac{Weight\ (lbs) \times 703}{Height^2\ (in)}$$

4. **Psychosocial Stress**

Psychosocial stress comprises diabetes-related stress, perceived stress and acculturative stress. In Hispanics/Latinos it is also important to include acculturation and acculturative stress for the differential

evaluation of the stress experience among immigrants and those born in the U.S. The corresponding

measures are the Perceived Stress Scale by Cohen, Kamarck, and Mermelstein (1983), the Diabetes

Distress Scale (DDS) developed by Polonsky, Fisher, Earles, Dude, Lees, Mullan, et al. (2005); and the

Hispanic Stress Inventory for Immigrants (Cavazos-Rehg, Zayas, Walker, & Fisher, 2006; Cervantes,

Padilla, & Salgado de Snyder, 1991) to measure acculturative stress.

Diabetes Distress Scale (DDS): I used the Diabetes Distress Scale (DDS) derived from the

Problem Areas in Diabetes (PAID), and developed and refined by Polonsky et al. (2005). Input collected

from patients, diabetes healthcare professionals and psychologists with diabetes experience informed the

creation of this instrument. An initial list of 50 items was streamlined to 17, and submitted to validity

and reliability testing on a multi-ethnic sample in four different clinical centers. Construct validity was

assessed by correlational analyses against depression assessed by the Center for Epidemiological Studies

Depression Scale (CES-D), diabetes self-care assessed by the Summary of Diabetes Self-care Activities

(SDSCA), and biomarkers A1C and lipids. With a Cronbach's alpha of 0.93, the DSS showed

"consistent, generalizable factor structure and good internal reliability and validity" across the four

clinics. Based on the feedback from patients and professionals, four subscales were developed to cover:

Emotional Burden, Physician-related Distress, Regimen-related Distress, and Diabetes-related

Interpersonal Distress. Emotional burden assesses the patient's feelings about the disease: "feeling

angry, scared and/or depressed when I think about living with diabetes"; Physician-related Distress

refers to concerns regarding professional care: "feelings that my doctor doesn't know enough about

diabetes and diabetes care"; Regimen-related Distress refers to concerns about the demands of self-

management: "feeling that I am often failing with my diabetes regimen"; and Diabetes-Interpersonal

Distress relates to the impact of diabetes on their relationships: "feeling that friends and family don't

give me the emotional support that I would like." Response categories range from 1 (no problem) to 6

(serious problem) on a 6-point Likert scale.

This scale has been translated into Spanish for application with Latino groups. Because of the high specificity and sensitivity of two of the items "feeling overwhelmed with the demands of living with diabetes" and "feeling that I am often failing with my diabetes regimen" (.87 and .95, respectively), researchers have suggested to use them to screen patients for diabetes- distress, and proceed to administer the full scale to those who screen positive for the two items (Fisher, et al., 2007). The scale has been translated into Spanish for application with Latino groups. To score the scale all items are added and then divided by 17. Separate scoring for each scale can narrow the focus on areas that require attention. When interpreting the scores, 3 or more in either a separate subscale or the whole scale, calls for clinical attention; between 2 and 2.9 is considered moderate distress, and less than 2 is little or no distress (Fisher, Hessler, Polonsky, & Mullan, 2012).

Perceived Stress Scale (PSS): Developed by Cohen, Kamarck, and Mermelstein (1983), this scale is widely used in community groups to evaluate general perception of stress, and measures the degree to which individuals assess life situations as stressful. This 14-item, 5-point Likert scale ranging from "0 = never" to "4 = very often" ranks how often respondents felt a particular way. Some items are: "In the last month, how often have you felt nervous and stressed?"; "In the last month, how often have you felt on top of things?" In the current study, I use the version of PSS that includes 10 questions. To obtain the total score, four out of the ten items (#s 4, 5, 7 and 8) are scored in reverse, and their sum is added to the sum of the other six items. PSS has adequate reliability (alpha = 0.78) and correlates well with other measures of life-event stress and social anxiety like the Job Responsibilities Scale (Cohen, 1983). It has been used in trials of stress management with older adults with type 2 diabetes (Surwit, 2002). The Spanish version of the scale has been found valid and reliable, and demonstrated adequate internal consistency (alpha= 0.83), and satisfactory cultural adaptation to a Mexican American sample (González-Ramírez & Landero-Hernández, 2007). A study by Kohut, McCann, Russell, Konopka, Cunnick, Franke, et al. (2006) showed improvement in PSS scores after the implementation of an

aerobic exercise plan among older adults at risk of type 2 diabetes. A study by Surwit and colleagues used the PSS to assess the impact of a stress management program on perceived stress among patients with diabetes. Participants experienced a significant reduction in A1C levels but their perceived stress scores did not improve significantly in comparison to non-diabetic controls. (Surwit, Van Tilburg, McCaskill, Parekh, Edwards, Williams, et al., 2002)

Hispanic Stress Inventory-for Immigrants: The Hispanic Stress Inventory is a measure of acculturative stress in immigrants, and captures the importance of social stressors. It includes five subscales, of which three address psychosocial aspects such as cultural and/or family conflict, parental stress and marital stress (Caplan, 2007). Its reliability and validity were originally measured on a community sample of 493. Two versions have been developed: one for immigrants with 73 items in 5 subscales (occupational/economic, parental, marital, immigration, and family/culture), and the other for U.S.-born Hispanics with 59 items in 4 subscales (occupational/economic, parental, marital, and family/culture). Scores for both versions correlated strongly with criterion measures of psychosocial stress. Measures of internal consistency and reproducibility yielded high reliability coefficients (Cervantes, Padilla, & Salgado de Synder, 1991). The abbreviated version of the HSI for immigrants has shown good internal consistency across all sub-scales from 0.68 to 0.83, and good convergent validity with measures of depression, anxiety and anger. This version includes two main factors captured in 17 items: Intra-familial Stress ("My children have not respected my authority the way they should", or "My spouse has not helped with household chores") and Extra-familial Stress ("Because I do not know enough English, it has been difficult to ne to interact with others", or "Because I am Latino I have been expected to work harder") and was tested in a sample of Midwestern Hispanic immigrants (Cavazos-Rehg, Zayas, Walker & Fisher, 2006). The internal consistency of these two factors was .86 for the Intra-familial Stress, and .87 for the Extra-familial Stress. The short version makes it application easier and more efficient. The inventory assesses the stressfulness of different issues on a 5-point Likert scale

that ranges from "1=not at all stressful" to "5=extremely stressful." The scores are added and then divided by 17 (Cavazos-Rehg et al., 2006). In our Tai Chi study, the 17-items were applied only to immigrants in the sample.

5. **Quality of Life**

I measure physical and mental health using the Healthy Days Measure developed by the Centers for Disease Control and Prevention (Moriarty, Zack, & Kobau, 2003).

HRQOL-14 – Healthy Days Measure: was developed for the assessment of health-related quality of life in populations. This measure includes four questions that ask about "self-rated general health and the number of days when a person has felt physically and mentally unhealthy, or limited in usual activities" (Moriarty, Zack, & Kobau, 2003). It has been useful in identifying population level health needs, disease and disability-related burden among subgroups. It has been used in several populations including the elderly and Hispanics; translations into multiple languages are available, including Spanish. This measure may serve to complement clinical measures of quality of life (SF-36), and it's widely used in research (Moriarty, Zack, & Kobau, 2003). The CDC's general health question is also present in the Short Form-version 2 of the 36-item questionnaire of the Medical Outcomes Study that assesses perceived general health status. Using the SF-36v2 researchers extracted two component summaries, the Physical (PCS) and Mental components (MCS), and compared the items in the CDC-questionnaire to these components for analysis. Principal components analyses of the CDC's questionnaire yielded two factors confirming the two main constructs of the questionnaire: the physical health and the mental health scales (Mielenz, Jackson, Currey, DeVellis, & Callahan, 2006; Horner-Johnson, Krahn, Andresen, Hall, & Rehabilitation Research & Training Center Expert Panel on Health Status Measurement, 2009). The general health question and items related to physical health (days of poor physical health and limitations due to physical or mental health) loaded on the first factor (physical

health) at absolute values of 0.74, 0.80, 0.78, respectively; the item related to mental health (days of poor mental health) loaded at 0.79 on the second factor (Mielenz et al., 2006). The physical and mental health scales significantly correlated with PCS and MCS, respectively ($r=.78$, $p=< .0001$ and $r=.71$; $p=< .0001$). Cronbach alpha for CDC-physical health scale was 0.84, and for the CDC-mental scale was 0.91 (Mielenz et al., 2006). These analyses were conducted in clinical samples with white and black populations. The results were confirmed by Horner-Johnson et al. (2009) when they evaluated BRFSS data from 2001 and 2002. These analyses yielded the same physical and mental health constructs. The four core items had a Cronbach's alpha of 0.708 in 2001 and 0.722 in 2002. Removing the mental health question increased the alpha, and removing any of the other items reduced the alpha. Also, in both years, the general health question showed significant correlation with the physical health score (2001: $r=0.86$, $p \leq 0.0001$; 2002: $r = 0.85$, $p \leq 0.0001$). The question correlated positively but weakly with the mental health score (2001: $r=0.17$, $p \leq 0.0001$; 2002: $r=0.18$, $p \leq 0.0001$). The questions also showed known-groups validity since people with diabetes had significantly lower scores on physical and mental health than people without the conditions. People ≥ 65 years or older showed significantly lower physical health but higher mental health than people aged 18 to 64 years. These results were consistent with previous research findings (CDC – MMWR, 2006; Horner-Johnson et al., 2009).

The general health question provides a Likert scale response and the five choices range from "Excellent" to "Poor". The three remaining questions inquire how many of the previous 30 days the person has felt physically or mentally ill, and the number of days poor physical or mental health have interfered with regular activities (job, etc.). The maximum possible number of days for each item is 30 days. When both physical and mental health days are reported, they are summed up and their combined score limited to a maximum of 30 days.

6. <u>Diabetes Self-care</u>

The Summary of Diabetes Self-Care Activities Measure is a self-reported questionnaire that uses 13 items to assess different aspects of diabetes self-care management (Toobert, Hampson, & Glasgow, 2000). This scale measures the number of days in the past seven days the patient engaged in a particular aspect of self-care (e.g., checking the feet, spacing carbohydrates, etc.). The areas included in our assessments are: general diet, specific diet, blood glucose monitoring (BGM), exercise, foot care, and smoking. Sample items include: "How many of the last seven days have you followed a healthful eating plan?"; "On how many of the last seven days did you participate in at least 30 minutes of physical activity?" (Total minutes of continuous activity, including walking); "On how many of the last seven days did you test your blood sugar?" In their evaluation of the scale on 1,988 older patients with type 2 diabetes, Toobert, Hampson, and Glasgow found high inter-item (mean=0.47) and moderate test-retest reliability (mean=0.40), and sensitivity to change. Correlations between the subscales although moderate in magnitude, were also positive. The validity of the subscales was confirmed by positive correlations with different measures of diet and exercise (mean=0.23). The scale showed strong ceiling effects and lack of variability on measures of medication taking. In my study, this subscale was modified to identify those taking pills, insulin, other injected meds, pills plus insulin, or no medication. The Spanish version has been found valid and reliable, with Cronbach's alpha of .68 and a test-retest correlation coefficient of 0.86 (Borges & Ostwald, 2007). In the current study, items on exercise and diet are treated as co-variates in data analysis.

7. <u>Morisky's Medication Adherence Scale</u>

This 8-item questionnaire assesses specific behaviors regarding medication taking; it assumes that several factors influence adherence to medication taking such as forgetfulness or complexity of the medication regimen (Morisky, Ang, Krousel-Wood, & Ward, 2008). The eight items include the 4-question scale previously developed by Morisky (1986) and expands on information about conditions

influencing medication adherence. A randomized 12-month trial of 1,367 hypertensive patients at a large teaching hospital served to evaluate the psychometric properties of the measure, its concurrent and predictive validity, and several psychosocial determinants of adherence such as social support, knowledge, complexity of the regimen and satisfaction with care. The population was poor, largely black, mean age was 52.5 years, almost 60% women, around half completed high school, and only 26% were married. Item-to-total correlation ranged from 0.3 to 0.59 for all items, with good internal consistency (Cronbach's alpha= 0.83). This 8-item measure correlated well with the previous 4-item scale (r= 0.64; $p < 0.05$). Confirmatory factor analysis showed one single factor and all items loaded well on it. The adherence scale and blood pressure control demonstrated a significant relationship (chi-square=6.6; $p < 0.05$). Using a cutoff point of <6, the sensitivity of the questionnaire to identify poor hypertension control was 0.93 and the specificity was 0.53 (Morisky et al., 2008). Knowledge, stress, coping, patient satisfaction and medication complexity were significantly associated with adherence. Persons with higher levels of knowledge of the medical treatment, satisfaction with medical care, high family social support, good coping skills, were significantly more likely to report high medication adherence. Lower medication adherence was associated with higher medical regimen complexity, poor health status and high levels of stress (Morisky et al., 2008). Although developed to assess medication adherence in hypertension, the scale has been adapted for use in multiple health conditions, including diabetes (Bailey, Barner, Weems, Leckbee, Solis, Montemayor, et al., 2012). In the current study we measure adherence to diabetes medications. The first seven questions inquire about situations that can favor non-adherence, and present answers as Yes=1 and No=0. The last question asks about the frequency of forgetting the medication, and the responses range from "Never" to "Always," and are organized in a 5-point Likert scale. Only responding "Never" receives a score of 1 point. All other responses are scored as 0. The score range for the adherence measure is 0 to 8 points, and higher numbers represent higher adherence. Scores determine three levels of adherence: high=8; medium=6-7; low=0-5 (Bailey, et al., 2012; Moriarty et al., 2008).

8. **Physical activity self-efficacy**

A short questionnaire assessing physical activity self-efficacy was developed by Bandura (2006) and adapted by Shen, Feng, Esperat, Irons, Chyu, Valdez, et al. (2007), in their feasibility study. This 5-item questionnaire assesses participants' perceived confidence in exercising when faced with potential obstacles to performing the activity, using a Likert scale that ranges from "1= very unsure" to "4= Very sure". Items include: "I can manage to perform my exercises even when I have worries and problems"; "… even when I am tired"; "… even when I am busy". Total scores are the sum of the five individual items. Internal consistency is very good (r=0.95) and the known-groups validity allows the instrument to differentiate practitioners from non-practitioners (t=-3.3, p=0.01). In the current study, I applied at pre- and post-test the same questionnaire used by Shen et al. (2007).

9. **Functional Social Support Questionnaire (FSSQ)**

This instrument assesses the perception of the amount of social support the individual receives in different situations. The original 14-item self-administered, multidimensional social support questionnaire derived from a larger questionnaire. It included four subscales for Quantity of Support, Instrumental Support, Affective Support and Confidant Support. It was evaluated at a family medicine clinic on 401 randomly selected white married females, younger than 45 and of high socio-economic status. The mean scores ranged from 3.54 to 4.34 on a 5-point scale (Broadhead et al., 1988). Test-retest reliability after two weeks gave a correlation of 0.66. Internal consistency varied from 0.5 to 0.85 for different items. The Instrumental Support scale did not show good internal consistency in factor analysis, so to improve instrument reliability the questionnaire was reduced to 8 items that included the Confidant Support and Affective Support scales. The two scales of Confidant support (5 items) and Affective support (3 items) demonstrated construct, concurrent and discriminant validity (Broadhead, Kaplan, James, Wagner, Schoenbach, Grimson, et al., 1983).

Reliability and validity of the scale were supported by a study in Spain in which factor analysis confirmed the two factors Confidant Support and Affective Support in a sample of 656 participants. In this study low social support was significantly associated with living alone, poor family function, chronic morbidity, and poor subjective health (Bellon Saameno, Delgado Sanchez, Luna del Castillo, & Lardilli, 1996). Other study also corroborated the association of social support with poor family function using the FSSQ (r=0.25; p <0.001) (Williams, Williams & Griggs, 1990). This study assessing the social support received by caregivers of children with disabilities at ages 4 and 6, added three items on Instrumental Support to seven items from the original scales Confidant Support and Affective Support. The study evaluated social support across several study sites and ethnicities: White, Black, Hispanic, Multiracial and Other. The internal consistency was excellent, with Cronbach's alpha ranging from 0.81 to 0.92. For Hispanics, alphas were 0.86 and 0.92 in two samples of 96 and 94 participants, respectively. A Likert scale from "1=As much as I would like" to "6=Much less than I would like" asked the participants to rate the support they get from "people who care what happens to me", or the "chances to talk to someone about problems at work or with my housework." In the current study, I used the 8-item questionnaire and scored the instrument using the mean values. Unlike other instruments in the set of questionnaires, a higher score represents less social support.

10. Tai Chi Acceptability

A short questionnaire assessed acceptability (Shen et al., 2007), barriers and facilitating factors to exercise, intention to continue long-term practice, and adherence to home practice. The questionnaire was used at six-weeks into the intervention and at post-test. This short questionnaire was created using information provided by participants in the preliminary focus groups prior to the randomized trial, and information collected by Shen et al. (2007) on their feasibility study of Tai Chi in patients with diabetes. I converted the factors obtained by Shen et al. in their participant interviews, into statements the participants had to identify as applicable to them by selecting one of two answers: "Yes" or "No". These

included the perceived benefits of the program, facilitating factors and barriers. Benefits included: "Feeling more relaxed," "Having more energy," "Sleeping better," etc. Negative experiences included: "Physical discomfort/pain/foot pain," "Difficulty of exercises," "Boring," etc. To get the score of the Acceptability of the program, the number of "Yes" in the Negative Experiences list was subtracted from the number of "Yes" responses to the list of Benefits.

The *Facilitating Factors* included location of the class site, access to transportation, bilingual instructor, etc. *Barriers* included location, transportation, time of day, not making friends, etc. The score for each subscale was equivalent to the number of "Yes" responses.

Intention to Continue Practice was assessed by a "Yes" or "No" response to the list of options: "Continue on my own," "Continue with a video," "Will take classes." *Adherence to Home Practice* was assessed by asking participants to select the number of days in the last seven days he/she had practiced the exercises at home, followed by the average number of minutes of practice each day. This provided an average number of minutes of practice per week that was used as covariate in regression analyses.

G. Human Subjects

The UIC Institutional Review Board #2 identified the study as Protocol #2010-0816, and approved it on December 6, 2012 (see Appendix G). The practice of physical activity may be considered a risk, but by applying sound screening procedures I ensured that those who ultimately engaged in physical activity did not increase their risk of suffering a complication during the course of the study. After the eligibility screening, a second screening using the adapted EASY tool assessed risk and served to identify potential participants requiring medical clearance. Those who required medical clearance were given letters requesting the approval of their physicians (see Appendix H). During the

intervention, data collection and management, I used precautionary measures to limit the potential risks for participants, as described below.

The assessment of A1C did not represent more than minimal risk since this was exactly the same procedure and required the same amount of blood necessary to measure glucose levels during home daily self-monitoring practice. Even though the assessments were done while participants were in a group, the measurement and disclosure of the actual A1C value, weight and blood pressure levels were done individually and in private.

Risk of injury during exercise was possible but all participants were briefed on safety tips and received a handout (see EASY Safety Tips) on recommendations for safe exercising. Rooms were comfortable, well ventilated, spacious, with even floors and minimal obstacles. Complaints about aching were minimal and the instructor provided tips to prevent it.

Patients with type 2 diabetes are usually familiar with the management of hypoglycemic episodes. However, participants were briefed on a protocol for the management of hypoglycemia during class (Cryer, 2008). They were advised to test their blood glucose levels and eat something prior to class. Refreshments and water were available at every class. One participant complained of weakness and dizziness; she was taken aside, given a sugary drink, and laid on the floor with legs up until dizziness subsided. She remained at rest for another 30 minutes, and received a substantial snack and sweet drinks (Cryer, 2008). I used a more conservative threshold for the definition of hypoglycemia since it is common for patients managing high glucose levels, to experience relative hypoglycemia at levels higher than 70 mg/dl (Cryer, 2008).

Personal information provided by participants remained private and was not accessed by other members of the group. Individuals were aware of other's people participation in the study, and they were advised to maintain confidentiality. Data collected were taken to the research center by the PI after every session. To comply with IRB requirements, paper forms were stored under secured cabinets at IHRP on the fifth floor. Electronic data were entered without identifiers and stored in secured servers.

IV. DATA MANAGEMENT AND ANALYSIS

A. <u>Data Collection</u>

I conducted data collection with occasional help from a community health worker from a community organization. Participants received the paper and pencil questionnaire in their preferred language (English/Spanish) and were given ample time (up to one hour) to answer on their own. Those with reading difficulties had the questionnaire read to them by me or my helper. Biomedical data (A1C, blood pressure, BMI) and the questionnaires were collected simultaneously in the same session. Once collected, questionnaires were brought to UIC and stored in secured metal cabinets. Once data collection was completed, a staff member entered the information in SPSS in a secured server, in preparation for analysis.

B. <u>Data Analysis</u>

Data analysis was performed using statistical software SAS (version 9.3, 2012, SAS Institute Inc.) and SPSS 20.0 for Windows (SPSS, Inc., Chicago, IL). Descriptive and inferential analyses were performed. All available data were included in the analysis. Intent- to- treat analyses were performed on the primary and secondary outcomes, using the last value carry-forward (LVCF) method, and re-assigning to the control group 2 participants who had moved to the treatment group. Significance level was set at $p=.05$.

Descriptive statistics included the mean and standard deviation for continuous variables (age, years of education, years living in the U.S., and years since diagnosis of diabetes) and frequency distributions for categorical variables: sex, income level, marital status, insurance status, employment, place of birth, language (see Table 4). Histograms were used for data presentation and summary.

Randomization was tested by comparing treatment and control groups at baseline using t-test for continuous variables (e.g., age, years of education, years since diagnosis, BMI, A1C, blood pressure, etc.); and chi-square test for categorical variables (e.g., sex, insulin use, marital status, place of birth, insurance, employment, etc.). Continuous variables that were significantly different between groups at the baseline analysis were treated as covariates in analysis of covariance (ANCOVA) models of change scores.

C. <u>Hypothesis Testing</u>

2: When compared to those receiving health education patients assigned to the Tai Chi program will have a:

(a) significant decrease in A1C levels;

(b) significant decrease in blood pressure; and

(c) significant decrease in psychosocial stress scores.

Each one of the aims of the study was treated as follows:

*1. To determine the impact of Tai Chi on A1C levels***:** We compared changes in A1C levels between the groups using a **random intercept linear model with group by time interaction.** Two sample, **2-sided t-tests** were used to compare changes in outcomes between baseline and 12-week follow-up between the intervention and the control groups without adjustment for baseline data. An **analysis of covariance** (ANCOVA), with A1C as the dependent variable, baseline A1C as the covariate, and treatment as the grouping variable was also conducted. Same separate analyses were conducted for the sub-group of immigrants. **Multiple regression** was used to describe the extent, direction, and strength of the relationship between the independent variables and A1C (Kleinbaum, Kupper, Nizam, & Muller, 2008). The model applied was

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_k X_k + \varepsilon,$$

where Y was the dependent variable of A1C, X_1 was the dummy variable coding for the dichotomous intervention groups (e.g., Control = 0 and Treatment = 1), and X_2 to X_k represented the different covariates (e.g., social support, physical activity self-efficacy, medical adherence, etc.). ε is the error term which follows a normal distribution with zero mean and variance s^2. To identify which set of predictor variables best explained A1C levels, I evaluated the correlations among variables, and those found to be significant were first included in the model. Then, all demographic variables and covariates were tested using forward selection. Regarding the stress scores, I assessed the correlation between each type of stress (perceived stress, diabetes distress, immigration-related stress), the co-variates (social support, physical activity self- efficacy, diet, exercise, healthy days, medication adherence) and A1C. The one(s) demonstrating significant correlation(s) were first included in the prediction model.

The model took on the following form:

$$A1C = \beta_0 + \beta_1(\text{Intervention}) + \beta_2(\text{PercStress}) + \beta_3(\text{DiabDistress}) + \beta_4(\text{SBP}) + \beta_5(\text{DBP})$$

$$+ \beta_6(\text{PASelf-effic}) + \beta_7(\text{SocSupp}) + \beta_8(\text{Diet}) + \beta_9(\text{Exercise}) + \beta_{10}(\text{MedAdh}) + \varepsilon.$$

Because of the small sample size, stepwise and forward selections were applied to identify the most appropriate predictor variables.

2. To determine the impact of Tai Chi on blood pressure levels: Data on blood pressure (BP) were collected as the average of three blood pressure measurements taken at pre- and post-test. The between-group difference in systolic and diastolic blood pressure change was analyzed using two-sample, 2-sided t-tests without adjustment for baseline data. This analysis was conducted for the whole

sample and for the immigrant sub-group. Within-group differences were assessed using t-tests comparing pre- and post-test values. The systolic (SBP) and diastolic (DBP) values were evaluated separately.

 3. *To determine the impact of Tai Chi on stress levels*. Psychosocial stress includes perceived stress, diabetes-related distress, and immigration-related stress (intra-familial and extra-familial stress sub-scales). These variables were analyzed separately since they measured different types of stress. Between-group differences in changes on perceived stress and diabetes-related distress were conducted using two-sample, 2-sided t-tests without adjustment for baseline data. Analyses on intra- and extra-familial stress were conducted only for the immigrant sub-group. T-tests were used to assess within-group differences between pre- and post-test values.

V. RESULTS

A. <u>Feasibility and Acceptability</u>

The acceptability of implementing Tai Chi in the community of Latino older adults was assessed by a questionnaire modeled after Shen et al. (2007). The questionnaire asked participants to answer yes/no to a list of potential positive/negative experiences, and facilitating factors/barriers related to their practice of Tai Chi. The questionnaire was given to participants at weeks 6 and 12. The first questionnaire sought to assess potential barriers to participation and level of acceptability of the practice in the middle of the course, while modifications to the intervention could still be incorporated if necessary. Twenty nine participants answered the mid-course questionnaire; and 31 completed the questionnaire at post-test. Table 4 summarizes the "yes" responses from those participants who completed the intervention. Some items in the questionnaire were not answered by all participants. In particular, the option referring to improvement in sex life did not apply to some of them and was left blank by many. Items that did not have any response are not included in the table (see Table 2).

The choice of class schedule, group format, location and instructor were informed by the previous focus group data collected prior to the initiation of this intervention. So, many of the potential barriers to participation had already been taken into account from the start.

TABLE II
ACCEPTABILITY AND FEASIBILITY OF TAI CHI IMPLEMENTATION (N=31)

Best experiences related to the practice of Tai Chi	Frequency	%
I feel I have more energy	30	96.8
I can move around more easily	30	96.8
I feel better in general	30	96.8
I feel more relaxed; this exercise reduces my stress	29	93.6
I feel more motivated to exercise	29	93.6
I sleep better	25	80.7
I feel it lowers my blood sugar	24	77.4
My sexual life has improved*	13	41.9
Worst experiences related to the practice of Tai Chi		
Physical discomfort/pain/feet hurt	5	16.3
Difficulty of exercises	5	16.3
Tiredness	4	12.9
Boring	2	6.5
Stressful	1	3.2
Blood sugar went up	1	3.2
Facilitating Factors		
Class in group format	28	90.3
Instructor's modeling of exercises and verbal guidance	27	87.1
Class time	27	87.1
Class location	27	87.1
Availability of parking	27	87.1
Made friends in class	27	87.1
Barriers		
Not enough instruction or modeling of exercises	4	12.9
Did not make friends in class	2	6.5
Transportation	1	3.2
Intention to exercise regularly from now on?		
Will continue on my own	31	100
Will join other class	27	87.1
Will continue with video	21	67.7

For the most part, participants had a favorable experience with Tai Chi, and were able to overcome barriers to attendance. Throughout the study the self-efficacy score of Tai Chi practice improved by 1.71 ($\pm$ 7.04), but the change was not significant (p= .186). The average number of days of attendance to Tai Chi classes was 13.6 out of 22 for 41 participants; the median was 16 days and the mode was 18 (see Table 3). From among those who completed post- test (N=31), the mean number of

days was 17 ($\pm$ 3.6), and the median and mode were 18 days. Twenty nine participants reported more than an hour of Tai Chi practice at home per week. Attendance to classes showed strong correlations with the summary score of facilitating factors/barriers to participation in class (r= 0.462; p=0.002), and with the summary score of positive/negative experiences during practice (r= 0.629; p<0.001). No other correlations were found.

TABLE III
ATTENDANCE OF PARTICIPANTS RECEIVING TAI CHI (N=41)

Variable	
Days attended class**, mean $\pm$ SD**	13.6 (6.97)
Minutes of practice per week, **mean $\pm$SD**	66.86 (35.7)

All the participants reported intention to continue practicing after the end of the study, although they differed in the ways they wanted to practice it. A phone call follow-up three months after the completion of the courses reached 20 participants, and confirmed that 13 of them were still practicing Tai Chi movements at home, and five were engaged in some other type of physical activity.

B. Demographics

The 49 participants enrolled in the study ranged in age from 50 to 80 years (mean= 60.6 years); were overweight or obese, and had a mean A1C of 8.0% ($\pm$1.5). The distribution of A1C values is presented in Figure 6. The Y axis is the number of participants, and the X axis is the A1C values. The curve shows that the distribution is slightly skewed to the left and the mean A1C value falls below 8.

Two outliers stand at the 12% and 14% mark but only the latter one falls outside of the curve. This participant was included in all analyses because similar cases are very likely to be found in community settings.
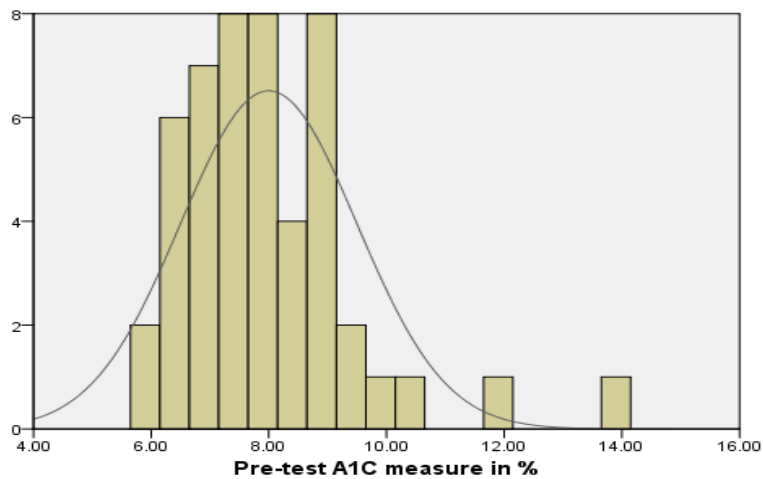
Figure 6. Distribution of Hemoglobin A1C Values in Total Sample of 49 Participants

The majority of the sample was female, was born in Mexico and had Spanish as their first language. Household income was low with about half of the sample living on less than $25,000 per year. The sample had less than 10 years of schooling on average. Almost as many participants were employed as were retired. At the time of the study, participants had lived with diabetes for about 9 years, 63% had insurance, and 36.7% rated their health fair or poor (N=18). Insulin alone or combined with oral medication was used by a quarter of the sample. Other demographic information and the baseline values for bio-behavioral variables are presented in Table 4.

TABLE IV
BASELINE CHARACTERISTICS

Variable	Total Sample	RC Pilot	All TC Participants
	N= 49	N= 40	N= 41
Age, years, **mean (SD)**	60.65 (7.8)	61.7 (7.8)	60.66 (8.3)
Sex			
Female, **n (%)**	32 (65.3)	24 (60.0)	30 (73.2)
Male, **n (%)**	17 (34.7)	16 (40.0)	11 (26.8)
Weight, **kg, mean (SD)**	189.3 (38.9)	194.3 (38.4)	189.4 (40.3)
BMI, **kg/m², mean (SD)**	33.99 (6.7)	34.8 (6.7)	34.5 (7.1)
A1C, %, **mean (SD)**	80.0 (1.5)	7.95 (1.5)	7.79 (1.2)
Blood pressure			
Systolic, **mm Hg, mean (SD)**	131.1 (21.3)	131.5 (20.4)	129.2 (21.0)
Diastolic, **mmHg, mean (SD)**	73.9 (8.9)	73.8 (8.8)	72.2 (9.3)
Years diagnosed with T2D, **years, mean (SD)**	9.1 (8.7)	9.9 (9.2)	9.1 (8.9)
Years of education, **years, mean (SD)**	9.7 (4.7)	9.9 (4.9)	9.9 (4.9)
Marital Status			
Married/Living together, **n (%)**	31 (63.3)	27 (76.5)	25 (60.98)
Single (Divorced/Separated/Widowed/ Never Married, **n (%)**	18 (36.7)	13 (32.5)	16 (39.0)
Place of birth			
US, **n (%)**	11 (22.4)	9 (22.5)	11 (26.8)
Mexico/Other, **n (%)**	38 (77.5)	31 (77.5)	30 (73.2)
Years living in the US, **years, mean (SD)**	43.4 (19.9)	36 (21.2)	35. (20.97)
Language			
English, **n (%)**	11 (22.4)	9 (22.5)	11 (26.8)
Spanish, **n (%)**	38 (77.6)	31 (77.5)	30 (73.2)
Insurance			
Yes, **n (%)**	31 (63.3)	27 (67.5)	28 (68.3)
No/Don't know, **n (%)**	18 (36.7)	13 (32.5)	12 (29.7)
Employment			
Employed for wages/Self-employed, **n (%)**	16 (32.7)	11 (27.5)	14 (34.1)
Out of work/Unable to work, **n (%)**	11 (22.4)	8 (20.0)	9 (22.0)
Homemaker, **n (%)**	7 (14.3)	7 (17.5)	6 (14.6)
Retired, **n (%)**	15 (30.6)	14 (35.0)	12 (29.3)
Household Income			
$\leq$ 24,999 per year, **n (%)**	23 (46.9)	21 (61.7)	19 (46.3)
$\geq$ 25,000 - $\leq$ 55,000, **n (%)**	11 (22.4)	13 (32.5)	11 (26.8)
Don't know/Not reported, **n (%)**	15 (30.6)	6 (15.0)	11 (26.8)
Number of days followed health eating plan, **mean (SD)**[1]	3.46 (2.5)	3.4 (2.5) ‡	3.8 (2.2)
Days per week followed eating plan last month, **mean (SD)**[1]	3.38 (2.7)	3.2 (2.6) ‡	3.9 (2.4)
Number of days ate 5+ servings F&V, **mean (SD)**[1]	3.45 (2.7)	3.4 (2.8)	3.8 (2.7)
Number of days ate high fat foods, **mean (SD)**[1]	3.1 (2.1)	3.3 (2.1) ‡	3.0 (1.9)
Number of days had $\geq$ 30 min. physical activity, **mean (SD)**[1]	2.84 (2.4)	2.6 (2.3)	2.95 (2.4)
Number of days participated in specific exercise, **mean (SD)**[1]	1.96 (2.6)	1.8 (2.4)	2.1 (2.6)
Number of days tested blood sugar, **mean (SD)**[1]	3.2 (3.1)	3.4 (3.1)	3.6 (3.1)
Number of days tested blood sugar as prescribed, **mean (SD)**[1]	2.7 (3.0)	2.95 (3.1)	3.0 (3.1)
Medication use[1]			
Pills, **n (%)**	28 (57.1)	23 (57.5)	25 (61.0)

Variable	Total Sample	RC Pilot	All TC Participants
	N= 49	N= 40	N= 41
Insulin alone/combined **n (%)**	12 (24.4)	10 (25.0)	9 (22.0)
Non/Not reported, **n (%)**	9 (18.4)	7 (17.5)	7 (17.0)
Diabetes Distress, **mean (SD)**[2]	1.88 (1.4)	2.02 (1.5)	2.02 (1.4)
Perceived Stress, **mean (SD)**[3]	14.81 (7.4)	15.8 (7.8) ‡	15.07 (7.5)
Hispanic Stress Inventory, **mean (SD)**[4]	1.8 (0.8) ^	1.96 (0.9) ^^	2.05 (0.9) ^^^
Financial Social Support, **mean (SD)**[5]	2.26 (2.5)	2.29 (1.6) ‡	2.36 (1.6)
Physical Activity Self-efficacy, **mean (SD)**[6]	12.88 (6.0)	11.8 (6.0) ‡	13.0 (5.2)
Medication Adherence, **mean (SD)**[7]	5.94 (2.1)	6.13 (1.9) ‡	5.85 (2.1)
General health			
Excellent/Very good, **n (%)**	8 (16.3)	5 (12.5)	9 (21.9)
Good, **n (%)**	12 (24.5)	10 (25.0)	16 (39.0)
Fair/Poor, **n (%)**	18 (36.7)	16 (40.0)	4 (9.8)
Not reported, **n (%)**	11 (22.4)	9 (22.5)	12 (29.3)
Number of days of physical illness in last 30 days, **mean (SD)**	1.9 (3.9)*	2.3 (4.5) ‡	3.2 (5.1)
Number of days of mental distress/illness, **mean (SD)**	2.8 (5.6)**	3.2 (6.3) ‡	3.2 (4.8)
Number of days limited by poor physical/mental health, **mean (SD)**	1.8 (4.5)***	1.9 (4.8)	2.7 (5.1)

[1]Range of scores for Diabetes Self-care activities: 0- 7 days

[2]Range of scores for Diabetes Distress Scale: 0 - 6, N=49

[3]Range of scores for Perceived Stress Scale: 1- 34, N=48

[4]Range of scores for Hispanic Stress Inventory: 1 – 4; N=45

[5]Range of scores for Functional Social Support: 1 - 6; N=48

[6]Range of scores for Physical Activity Self-efficacy: 0 – 20; N=48

[7]Range of scores for Morisky's Medication Adherence: 2 – 8. N=47.

^ N= 38

^^ N= 31

^^^ N= 30

* N=17

** N=19

*** N=10.

‡ N <40 due to missing values

C. Randomized Controlled Pilot

 1. Baseline

  The first 40 participants enrolled in the study were randomized into treatment and control groups (see Table 5). After randomization the treatment group had significantly more participants with insurance coverage than the control, and reported more days with limitations by physical or mental health problems. Years of education were higher in the treatment group and A1C was higher in the control group but these differences were not significant. Similar analyses in the sub-group of immigrants showed a significant difference in medication with a larger proportion receiving pills in the treatment group; health insurance was also higher in the treatment group but did not reach significance. Among immigrants there were no differences in baseline A1C. These results are shown in Appendix K, Table 5A. The intent- to-treat analysis re-allocated two participants (# 30 and 32) in the control group. It showed that after randomization none of the variables mentioned above were significantly different between groups (see Appendix L, Table 5B).

TABLE V
BASELINE CHARACTERISTICS OF RANDOMIZED CONTROLLED PILOT –
TAI CHI AND CONTROL GROUPS

Variable	Tai Chi	Control	*P* value
	N= 22	N= 8=18	
Age, **years, mean (SD)**	61.6 (9.0)	61.8 (6.3)	0.94
Sex			
Female, **n (%)**	14 (35.0)	10 (25.0)	0.60
Male, **n (%)**	8 (20.0)	8 (20.0)	
Weight, **kg, mean (SD)**	192.45 (39.9)	196.5 (37.6)	0.74
BMI, **kg/m², mean (SD))**	35.25 (6.9)	34.23 (6.6)	0.64
A1C, %, **mean (SD)**	7.55 (1.2)	8.44 (1.7)	0.056**
Blood pressure			
Systolic, **mm Hg, mean (SD)**	131.0 (22.1)	132.0 (18.8)	0.89
Diastolic, **mmHg, mean (SD)**	73.9 (9.5)	73.7 (8.1)	0.93
Years diagnosed with T2D, **years, mean (SD)**	9.0 (9.7)	11.1 (8.6)	0.48
Years of education, **years, mean (SD)**	11.1 (5.4)	8.4 (3.9)	0.08**
Marital Status			
Married, **n (%)**	16 (40.0)	11 (27.5)	0.83
Single (Divorced/Separated/Widowed, **n (%)**	6 (15.0)	7 (17.5)	
Place of birth			
US, **n (%)**	5 (22.7)	4 (22.2)	0.65
Mexico/Other, **n (%)**	17 (77.3)	14 (77.8)	
Years living in the US, **years, mean (SD)**	34.5 (23.6)	37.5 (16.9)	0.66
Language			
English, **n (%)**	7 (17.5)	2 (5.0)	0.12
Spanish, **n (%)**	15 (37.5)	16 (40.0)	
Insurance			
Yes, **n (%)**	18 (45.0)	9 (22.5)	0.048*
No/Don't know, **n (%)**	4 (10.0)	9 (22.5)	
Employment			
Employed for wages/Self-employed, **n (%)**	6 (15.0)	5 (12.5)	0.74
Out of work/Unable to work, **n (%)**	5 (12.5)	3 (7.5)	
Homemaker, **n (%)**	4 (10.0)	3 (7.5)	
Retired, **n (%)**	7 (17.5)	7 (17.5)	
Household Income			
$\leq$ 24,999 per year, **n (%)**	11 (27.5)	10 (25.0)	0.17
$\geq$ 25,000, **n (%)**	6 (15.0)	3 (7.5)	
Don't know/Not reported, **n (%)**	5 (12.5)	5 (12.5)	
Number of days followed health eating plan, **mean (SD)**	3.50 (2.2)	3.24 (2.8)	0.75
Days per week followed eating plan last month, **mean (SD)**	3.59 (2.4)	2.69 (2.8)	0.29
Number of days ate 5+ servings F&V, **mean (SD)**	3.59 (2.9)	3.11 (2.6)	0.59
Number of days ate high fat foods, **mean (SD)**	3.43 (2.0)	3.17 (2.3)	0.71
Number of days had $\geq$ 30 min. physical activity, **mean (SD)**	2.19 (2.1)	3.17 (2.4)	0.19
Number of days participated in specific exercise, **mean (SD)**	1.41 (2.3)	2.22 (2.6)	0.30
Number of days tested blood sugar, **mean (SD)**	4.05 (3.2)	2.67 (2.9)	0.16
Number of days tested blood sugar as prescribed, **mean (SD)**	3.77 (3.4)	1.94 (2.4)	0.16
Medication use			
Pills, **n (%)**	3.77 (3.4)	1.94 (2.3)	0.059**
Insulin alone/combined **n (%)**	16 (40.0)	6 (15.0)	

Variable	Tai Chi	Control	*P* value
	N= 22	N= 8=18	
Non/Not reported, **n (%)**	4 (10.0)	6 (15.0)	
Diabetes Distress, **mean (SD)**	2 (5.0)	5 (12.5)	
Perceived Stress, **mean (SD)**	2.24 (1.4)	1.74 (1.6)	0.29
Hispanic Stress Inventory, **mean (SD)**	17.41 (8.7)	13.62 (6.1)	0.14
Financial Social Support, **mean (SD)**	2.08 (1.1)	1.81 (0.8)	0.43
Physical Activity Self-efficacy, **mean (SD)**	2.16 (1.4)	2.45 (1.90)	0.59
Medication Adherence, **mean (SD)**	12.14 (5.5)	11.44 (6.7)	0.73
General health			
Excellent/Very good, **n (%)**	3 (13.6)	2 (11.1)	0.10
Good, **n (%)**	7 (31.8)	3 (16.7)	
Fair/Poor, **n (%)**	10 (44.44)	6 (3.33)	
Not reported, **n (%)**	2 (9.1)	7 (38.9)	
Number of days of physical illness in last 30 days, **mean (SD)**	3.21 (5.5)	1.14 (2.0)	0.19
Number of days of mental distress/illness, **mean (SD)**	3.45 (5.2)	2.81 (7.6)	0.77
Number of days limited by poor physical/mental health, m**ean (SD)**	3.33 (6.2)	0.18 (.73)	0.0434*

***Denotes significance at p =0.05 level

** Denotes trend toward significance

a. __Correlations__

Baseline correlations for the main and secondary variables were assessed. In the RC pilot, A1C showed a positive correlation with the number of days participants exercised for at least 30 minutes during the previous seven days (.392; p=.014). Systolic blood pressure was associated with age (.515; p=.001), length of diabetes (.522; p=.001) and negatively correlated with diabetes-related distress (-.340; p=.032); diastolic blood pressure was significantly correlated with weight (.407; p=.009) and with systolic blood pressure (.414; p=.003).

Diabetes-related distress was positively correlated to perceived stress (.535; p<.0001), intra/extra familial stress (.434; p=.015), low social support (.464; p=.003), and the number of days limited by poor physical or mental health (.429; p=.007) but negatively correlated with age (-.433; p=.005) and systolic blood pressure. Perceived stress was positively associated with intra/extra-familial stress (.398; p=.026), in particular with intra-familial stress (.529; p=.002), with the number of days of poor mental health (.401; p=.015), and with number of days limited by poor mental or physical health (.523; p= .001); but it was also negatively associated with age (-.475; p=.002).

Intra/extra-familial stress was also positively associated with low social support (.508; p=.004), and negatively associated with years of education (-.441; p=.013), medication adherence (-.508; p=.004), and number of days exercising at least 30 minutes (-.428; p=.028). Intra/extra-familial stress was also strongly associated with all measures of quality of life: the number of days of poor physical health (.392; p=.014); days of poor mental health (.479; p=.002), and number of days limited by poor physical or mental health (.453; p=.003).

b. **Regression Analyses**

Multiple linear regression analyses on baseline A1C found that only the number of days the participants engaged in at least 30 minutes of exercise (EXER5PRE) was a significant predictor of A1C (p= .0136). Other variables tested in the model were not significant (age, sex, BMI, number of years since diabetes diagnosis).

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Intercept	7.269073743	0.34053886	21.35	<.0001
EXER5PRE	0.253457515	0.09778414	2.59	0.0136

Figure 7. Computer Output – Regression on Baseline A1C – Randomized Controlled Pilot

Multiple linear regression on baseline diabetes distress showed that perceived stress (PSS_PRE_SCORE) (p = .0014) and low social support (FSSQ_PRE_SCORE) (p =.0089) were significant predictors. Demographic variables were not significant predictors.

Other variables (systolic and diastolic blood pressure, perceived stress, and immigration-related stress) had no significant predictors at baseline in the Randomized Controlled Trial groups.

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Intercept	-.1271142846	0.46847009	-0.27	0.7877
PSS_PRE_SCORE	0.0867598137	0.02504038	3.46	0.0014
FSSQ_PRE_SCORE	0.3308412907	0.11953256	2.77	0.0089

Figure 8. Computer Output – Regression of Baseline Diabetes Distress – Randomized Controlled Pilot

D. <u>Randomized Control Pilot Outcomes</u>

A1C. Both groups demonstrated reduction in A1C, with no significant difference between them. The linear mixed model of A1C with random intercept with time by group interaction showed no significance (p= .629) (see Figure 11). The initial value of A1C in the control group was higher than in the treatment group and the reduction was slightly larger as well. Both groups showed attrition but the numbers were equivalent at the end (see Table 6).

ANCOVA adjusting for A1C baseline values was not significant (p= .925). When analyses were conducted eliminating the outlier (A1C=14%) in the control group, the pre-test mean A1C value for the whole sample (N=48) was reduced to 7.87%, and to 8.12% for the control group. However, the differences between groups remained non-significant (p=.12). Intent-to-treat analyses did not change significantly the results either (p=.30) (see Table 7).

Multiple linear regression analyses found no significant predictors of change in A1C. Variables included age, sex, BMI, years since diabetes diagnosis and number of days engaged in exercise for at least 30 minutes.
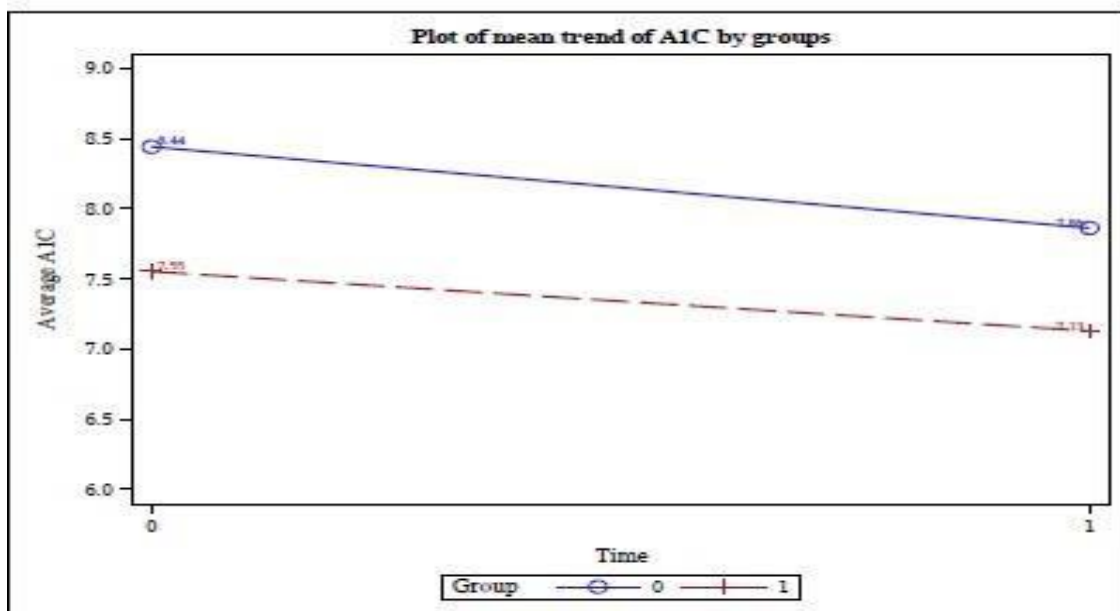
Figure 9. Linear Mixed Model of A1C on Time and Group – Random Intercept with Time by Group Interaction – Plot of the Mean Trend of A1C

1. **Blood Pressure**

At the 12-week post-test participants in the treatment and control groups showed slight reductions in systolic and diastolic blood pressure that did not reach statistical significance (p=.92 and .59, respectively). Linear mixed models with time by group interaction were not significant (p=.849 for systolic blood pressure; p=.477 for diastolic blood pressure). Intent to treat analyses did not change the results (see Table 7). Change in systolic blood pressure was predicted by weight only (p=.0085). Other variables in the model were not significant (age, years since diabetes diagnosis, and the combined days of physical and/or mental illness). Regression on change in diastolic blood pressure did not show predictors.

2. **Diabetes-related Distress**

At post-test there were no significant differences between treatment and control groups in reported levels of diabetes related distress (p=.35). The linear model with time by group interaction

was not significant either (p=.257). The control group showed a slight increase in scores, and the intervention group showed no improvement. Intent-to-treat analyses did not change the results (p= .34). The multiple linear regression on change in diabetes distress did not identify any significant predictors. Variables included in the model were not significant (age, A1C, sex, and social support).

3. Perceived Stress

At post-test perceived stress did not show significant differences between groups for the whole sample (p=.57). The linear model with time by group interaction was not significant (p=.318). Both control and Tai Chi groups showed slight increase in scores by the end of the study. Intent- to-treat analyses confirmed the results (p=.15). The regression model for the change in perceived stress included age, diet, exercise, the combined days of physical and/or mental illness, and physical activity self-efficacy, but they were not significant. PSS however, showed a trend toward significance in the random intercept linear model with group by time interaction among immigrants (p=.0655).

4. Immigration-related Stress

Of the 49 participants, 38 were immigrants (mostly from Mexico) and only 11 were U.S.-born (see Table 4). The subgroup of immigrants was evaluated separately to assess levels of stress associated with immigration status using the Hispanic Stress Inventory for Immigrants measuring intra- and extra-familial stress. Immigrants from both the treatment and control groups showed decreased scores in intra/extra-familial stress at post-test; the treatment group showed twice the reduction than the control group. However the differences did not reach statistical significance (p= .29). Intent-to-treat analyses did not change the results (p= .27). The linear model with time by group interaction showed no significance (p=.329). Regression analyses showed no predictors.

TABLE VI

OUTCOMES OF RANDOMIZED TAI CHI AND CONTROL GROUPS –
RANDOMIZED CONTROLLED PILOT

Outcome Measures	No.	Mean (SD)		Change (95% CI)		P
		Baseline	12-Week	Within-Group	Control	
Primary Outcome						
A1C, %						
Control	14	8.29 (1.01)	7.95 (0.71)	-0.34 (-0.68 to 0.01)	0 (Reference)	0.62
Intervention	14	7.36 (1.09)	7.13 (0.87)	-0.24 (-0.49 to 0.02)	0.10 (-0.31 to 0.51)	
Secondary Outcomes						
Systolic Blood Pressure, mm Hg						
Control	13	130.2 (21.74)	125.5 (14.67)	-4.64 (-14.33 to 5.06)	0 (Reference)	0.92
Intervention	14	131.0 (21.70)	127.0 (18.90)	-4.06 (-11.30 to 3.19)	0.58 (-10.88 to 12.04)	
Diastolic Blood Pressure, mm Hg						
Control	13	73.58 (9.48)	66.66 (7.06)	-6.92 (-13.98 to 0.14)	0 (Reference)	0.59
Intervention	14	74.41 (9.38)	69.76 (6.33)	-4.64 (-10.31 to 1.03)	2.27 (-6.28 to 10.83)	
Diabetes-related Distress						
Control	14	1.62 (1.39)	2.06 (1.59)	0.44 (-0.18 to 1.06)	0 (Reference)	0.35
Intervention	14	2.08 (1.28)	2.08 (1.37)	-0.0009 (-0.78 to 0.78)	-0.44 (-1.38 to 0.51)	
Perceived Stress						
Control	14	14.50 (7.21)	17.38 (6.35)	2.88 (-0.48 to 6.23)	0 (Reference)	0.57
Intervention	14	15.58 (8.71)	17.00 (8.60)	1.42 (-3.08 to 5.91)	-1.46 (-6.69 to 3.77)	
Immigration-related Stress						
Control	13	1.89 (0.92)	1.68 (0.81)	-0.22 (-0.57 to 0.14)	0 (Reference)	0.29
Intervention	11	2.33 (1.17)	1.84 (0.79)	-0.49 (0.91 to -0.07)	-0.27 (-0.79 to 0.25)	

TABLE VII

INTENT-TO-TREAT ANALYSES – RANDOMIZED CONTROLLED PILOT

Outcome	No.	Mean (SD)		Change (95% CI)		P
		Baseline	12-Week	Within-Group	Control	
Primary Outcome						
A1C, %						
Control	20	8.36 (1.63)	8.08 (1.56)	-0.28 (-0.52 to -0.03)	0 (Reference)	0.30
Intervention	20	7.56 (1.21)	7.43 (1.10)	-0.12 (-0.29 to 0.04)	0.15 (-0.41 to 0.44)	
Secondary Outcomes						
Systolic Blood Pressure, mm Hg						
Control	20	131.12 (18.07)	128.88 (14.35)	-2.24 (-7.32 to 2.85)	0 (Reference)	0.85
Intervention	20	131.78 (23.03)	128.91 (21.46)	-2.87 (-7.80 to 2.06)	-0.64 (-7.48 to 6.21)	
Diastolic Blood Pressure, mm Hg						
Control	20	73.96 (7.77)	70.66 (7.65)	-3.30 (-7.60 to 1.00)	0 (Reference)	0.94
Intervention	20	73.65 (9.89)	70.56 (8.21)	-3.08 (-7.04 to 0.87)	0.22 (-5.43 to 5.86)	
Diabetes-related Distress						
Control	20	1.71 (1.53)	1.36 (0.91)	-0.35 (-0.90 to 0.19)	0 (Reference)	0.34
Intervention	20	2.32 (1.39)	2.31 (1.44)	-0.003 (-0.52 to 0.52)	0.35 (-0.38 to 1.08)	
Perceived Stress						
Control	19	14.11 (6.38)	12.11 (6.67)	-2.00 (-4.19 to 3.19)	0 (Reference)	0.15
Intervention	20	17.50 (8.82)	17.95 (8.40)	0.45 (-2.29 to 3.19)	2.45 (-0.96 to 5.86)	
Immigration-related Stress						
Control	15	1.76 (0.76)	1.68 (0.81)	-0.14 (-.36 to 0.08)	0 (Reference)	0.27
Intervention	16	2.15 (1.05)	1.81 (0.72)	-0.34 (-0.63 to -0.04)	-0.20 (-0.56 to 0.16)	

E. All Tai Chi Participants

    1. Baseline

A separate set of pre/post-test analyses was conducted for the group comprised of all the participants (randomized and non-randomized) who received the Tai Chi intervention at any time throughout the study. A total of 41 participants constituted this group, of which 31 completed post-test. The baseline characteristics of the group are presented in Table 4.

        a. Correlations

Baseline correlations for those who received Tai Chi showed that A1C at pre-test was positively associated to medication use (.356; p=.0224), and negatively correlated to medication adherence (-.438; p=.0047). Systolic blood pressure positively correlated with diastolic blood pressure (.486; p=.0013), age (.443; p=.0037), and length of diabetes diagnosis (.452; p= .003). Diastolic blood pressure was associated with number of days of blood glucose monitoring (.327; p=. 0397). Diabetes-related distress negatively correlated with age (-.421; p=.0061); but positively with perceived stress (.0.666; p< .0001); low social support (.420; p= .0063), immigration related stress (.477; p=.0089), and days of poor physical health (.347; p=.0479) and limitations due to poor mental/physical health (0.450; p=.0046). Perceived stress negatively related to age (-.437; p=.0043), physical activity self-efficacy (-.338; p=.0308), the number of days eating fruits and vegetables (-.33; p=.035), and number of days participating in exercise (-.417; p=.0075). However, perceived stress was positively correlated with the number of days eating high fat foods (.360; p=.0224), immigration-related stress (.501; p=.0057), days of poor mental health (.396; p= .0153), and days of limitations due to poor physical or mental health (.552; p= .0003). Besides other correlations mentioned above, immigration-related stress was associated positively with low social support (.582; p=.0009), and negatively associated with the number of days practicing exercise (-.391; p=.0399).

b. **Regression Analyses**

Multiple linear regression found that the use of insulin alone or in combination with pills (Med Insulin/Combined) (p=.0159) and lack of medication adherence (MMS_PRE_SCOR) (p=.0063) were significant predictors of A1C (see Figure 10).

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Intercept	8.871631076	0.53102420	16.71	<.0001
Med	0.991938360	0.39196133	2.53	0.0159
Med None	0.893099822	0.47685382	1.87	0.0692
Med Pills	0.000000000	.	.	.
MMS_PRE_SCOR	-0.239535415	0.08257699	-2.90	0.0063

Figure 10. Computer Output – Regression on Baseline A1C – All Tai Chi Participants

Systolic blood pressure was predicted by diastolic blood pressure (DIAPRE_c), age (AGE_c), and years diagnosed with diabetes (DIABSTAT) (see Figure 11).

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Intercept	120.238034	3.57946177	33.59	<.0001
AGE_c	0.8749209	0.32274800	2.71	0.0101
DIABSTAT	0.6535488	0.30204084	2.16	0.0370
DIAPRE_c	1.1204296	0.25862021	4.33	0.0001

Figure 11. Computer Output – Regression on Systolic Blood Pressure at Baseline – All Tai Chi Participants

With age centered at 60 yrs., systolic blood pressure centered at 120 mm Hg and diastolic blood pressure centered at 70 mm Hg, for every year of being diagnosed with diabetes, SBP increased by .65 mm Hg. For every year above 60, SBP increased by .87 mm Hg, and for every increase in DBP above 70, SBP goes up by 1.12 mm Hg.

Regression analyses on diastolic blood pressure and psychosocial stress variables did not show significant predictors. As mentioned above, variables included in each model were those correlated with the dependent variable, the demographic variables and the covariates.

F. All Tai Chi Participants Outcomes

1. Primary and Secondary Outcomes

The 31 participants who received the intervention and completed post-test demonstrated a significant change in A1C from a pre-test value of 7.63% ($\pm$0.94) to 7.35% ($\pm$0.78) at post-test. Twenty one participants (67.7%) experienced a reduction in A1C ranging from -0.1% to -2.0%. For this sample, the mean reduction of 0.28% was significant (p=.017) (see Table 8). Results of intent-to-treat analyses confirmed the significant difference (p=.0176) (see Appendix M).

I conducted further analyses comparing All Tai Chi Participants (N=41) with those in the control group from the Randomized Controlled Pilot (N=18). The A1C reduction of 0.28% ($\pm$ 0.61) in the TAI Chi Participants was not significantly different from the reduction of 0.34% ($\pm$0.59) in the control group (p= .77).

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Intercept	0.2292133021	0.27277043	0.84	0.4078
DIAPST_c	0.0199934867	0.00904351	2.21	0.0354
PRACTIMEPST	-.0377692909	0.01638346	-2.31	0.0288

Figure 12. Computer Output – Regression on Change in A1C – All Tai Chi Participants

Multiple linear regression analyses found that Tai Chi practice time per week at posttest (PRACTIMEPST), and change in diastolic blood pressure (DIAPST) were predictors of change in A1C (see Figure 12).

Systolic and diastolic blood pressure showed no significant changes at post-test (p= .71 and .42, respectively) (see Table 8). Perceived stress did not demonstrate significant changes at post-test (p= 0.53), but diabetes-related distress did show significant reductions (p= .046) confirmed by intent-to-treat analyses (see Appendix M). Regression analyses on diabetes distress change did not yield predictors.

Immigration-related stress showed significant changes (p= .0055) (see Table 8). A more detailed analysis showed that reduction in extra-familial stress led the change (p= .037). Intent-to-treat analyses confirmed the results (see Appendix M). At post-test, intra-familial stress was correlated with perceived stress (0.507; p= .019), diabetes distress (0.587, p= .005) and negatively correlated with post-test medical adherence (-0.433; p= .05). Post-test extra-familial stress showed significant correlations with diabetes distress (0.507; p=0.016), and BMI (0.425; p= 0.043); and negatively correlated with the summary score of facilitating factors for participation in class at post-test (-0.466; p= .025). Regression analysis showed that increasing the consumption of fruits and vegetables (DIET3_ch) and increasing

participation in exercise (EXER6_ch) predicted reduction in immigration-related stress. Other variables

in the model included demographic variables and covariates (see Figure 13).

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Intercept	-.1240368557	0.09579174	-1.29	0.2072
DIET3_ch	-.0770693070	0.03919102	-1.97	0.0604
EXER6_ch	-.0906318409	0.02972569	-3.05	0.0054

Figure 13. Computer Output – Regression on Change in Immigration-related Stress – All Tai Chi
Participants

TABLE VIII
PRE-POST-TEST CHANGES OF ALL TAI CHI PARTICIPANTS

Outcome Measures	N	Mean (SD)		Change (95% CI)	P
		Baseline	**12-week**	**Within-Group**	
Primary Outcome					
A1C, %	31	7.63 (0.94)	7.35 (0.78)	-0.28 (-.05 to -.054)	0.017*
Secondary Outcomes					
Systolic Blood Pressure, mm Hg	31	127.3 (20.2)	128.4 (20.8)	1.12 (-4.96 to 7.19)	0.71
Diastolic Blood Pressure, mm Hg	31	72.1 (9.4)	74.0 (11.06)	1.94 (-2.9 to -6.78)	0.42
Diabetes Distress	31	1.96 (1.42)	1.49 (1.3)	-0.47 (-.93 to -.01)	0.046*
Perceived Stress	31	14.13 (7.0)	13.48 (7.1)	- 0.65 (-2.74 to 1.45)	0.53
Immigration-related Stress	23	2.05 (0.90)	1.74 (0.65)	- 0.36 (-.61 to -.12)	0.0055*

*Denotes significance at p =0.05 level.

G. Sample Size

Prior to the publication of the meta-analysis by Lee (2015), I evaluated several Tai Chi intervention studies to calculate a reasonable sample size for this pilot (see Table 9). For the choice of the control group intervention I used the meta-analysis by Umpierre et al. (2011).

TABLE IX
TAI CHI STUDIES

Tai Chi Studies	Follow-up Time	Intensity	Change in A1c	SD	Effect size	Total N
Liu et al., 2009	12 weeks	3/week	-0.32	0.26	1.32	20
Shen et al., 2007	12 weeks	2/ week	- 1	1.4	0.71	62
Song et al., 2009	12 weeks	2/ week	- 0.44	0.78`	0.56	79
Yeh et al., 2007	12 weeks	3/ week	- 0.46	1.35	0.34	270

The selection shows that a small sample size of even 20 participants as in Liu, Miller, Burton, and Brown (2009) may give significant results with a change in A1C of -0.32% (p=.002), and a SD= 0.26. This study assessed the effect of Tai Chi on A1C after 12 weeks of intervention, with three 1.5-hour sessions per week. In my study, the intervention was two 1-hour sessions per week for 12 weeks. For the control group, Umpierre et al (2011) found that physical activity advice does not have significant effect on A1C unless it is combined with dietary advice. In my study, it was reasonable to assume that there would be no change from baseline to post-test in the control group since I was not incorporating dietary advice.

Assuming similar conditions to those of Liu et al. (2009) (change in A1C= 0.32% +0.26), with alpha set at .05, and 80% power, I expected to find detectable differences between the treatment and control groups with an N=24. In the actual sample, the difference between the means was 0.11% +0.31. Under these conditions, with alpha = .05 and 80% power, the number of participants necessary to reach significance would have been N=252. These calculations were made using http://hedwig.mgh.harvard.edu/sample_size/js/js_parallel_quant.html.

VI. DISCUSSION

This study tested the feasibility of implementing Tai Chi as a stress reduction and physical activity option for Hispanic/Latino older adults with diabetes, and compared the intervention to a control group to assess its impact on glycemic levels, blood pressure and markers of psychosocial stress. Such undertaking required preliminary assessments of the factors that could influence the receptivity of this unfamiliar practice among Hispanics. Six focus groups queried 27 Hispanic older adults on issues such as their perception of stress, their diabetes-related experience of stress, social and family support, physical activity and coping practices. The participants also offered specific information about their reasons for acceptance of Tai Chi and what they considered the ideal conditions for the implementation of Tai Chi classes.

Surprisingly, participants showed openness and receptivity to Tai Chi as a new type of exercise; they welcomed the smooth, slow movements in contrast to popular modalities of more intense physical activity, and did not express concerns or misgivings in experimenting or adopting a practice unfamiliar to their own culture.

Participants' recommendations informed the theoretical framework that guided the planning and implementation of the intervention and the randomized trial. Conditions requested by the focus groups that could facilitate program implementation and make the Tai Chi practice more culturally appropriate to the Hispanic/Latino groups included: a group format, a venue with easy access and free parking, a bilingual instructor, classes scheduled at the end of the day, and group sessions that allowed the participation of family members.

The focus of the second phase of the study was to demonstrate the feasibility of implementing such program, and its potential measurable benefits for Hispanic older adults with type 2 diabetes.

Hypothesis 1 stated that the implementation of a Tai Chi program for Hispanic older adults with diabetes would be feasible. Participants reported a positive experience with the program, with the majority of them attending at least 18 out of 22 classes. Attendance to classes was influenced by the positive experiences associated with the practice, and by the end of the program more than 70% of the group was practicing at home for an hour or more. Although it did not reach significance, Tai Chi self-efficacy increased and may have influenced adherence to practice. The implementation of the Tai Chi program for Hispanic older adults with diabetes, proved feasible. The recommendations from the focus groups were relatively easy to implement. The result was an intervention that was well accepted and enjoyable to the majority of participants. The pace of the classes and the movements were in agreement with the recommendations of those who felt that they "had already run what they had to run" in life.

The experiences in my study reflected those by Shen et al. (2007) in their pilot assessing the feasibility of implementing Tai Chi Yang style. Shen et al.'s study recruited participants from the community, conducted the 60 minute-intervention twice per week for 12 weeks, and evaluated the effects on levels of A1C. They collected information from participant interviews about facilitating factors and obstacles to class participation, and together with our responses from the preliminary focus groups, we used to create a questionnaire that served to rate Hispanic participants' acceptance of my intervention. Shen et al.'s study found that the most common positive experiences reported by participants were the feeling of relaxation, increased energy, and lowered sugar levels. The most common negative experience was discomfort or pain. The most common facilitating factors were the instructor's modeling and verbal persuasion, time and location. These last two were also the most common difficulties reported. Most of the participants (54%) reported their intention to continue Tai Chi on their own after the end of the program (Shen et al., 2007). Except for the perception of lowered sugar levels, the responses from the Hispanic participants in my study supported the observations by Shen et al.

Like in Shen's pilot, Tai Chi self-efficacy raw scores increased but failed to reach statistical significance in my study (Shen et al., 2007). The relationship of self-efficacy and Tai Chi has been studied by several authors (Li, et al, 2001a; Li, Harmer, McAuley, Fisher, Duncan, & Duncan, 2002b; Dechamps, Lafont, & Bourdel-Marchasson, 2007; Tousignant, Corriveau, Roy, Desrosiers, Dubuc, Hebert, et al., 2012). A randomized trial by Li (2001) compared 49 older adults receiving Tai Chi instruction twice a week for 6 months, to 45 participants in a wait-list control group. They found that the practice of Tai Chi increased self-efficacy and perceived physical function, and that these changes were related to one another (Li, et al,, 2001b). My study did not include a measure of actual or perceived physical function, but several participants anecdotally reported improvement in mobility, stability and sense of confidence. One participant reduced the use of her cane for support and increased standing time during the practice and in daily activities. Like in Shen et al.'s (2007) study, the small sample size and the short intervention (12 weeks) in my study may have contributed to the lack of significant change in self-efficacy (p=.186). Li's study had a larger sample size and provided ample time (six months) to observe important associations and significant outcomes (Li, et al., 2001b).

Hypothesis 2 tested that Tai Chi practice for 12 weeks would improve A1C, blood pressure and psychosocial stress. Two sets of analyses were conducted to address this hypothesis. The results of the randomized pilot trial (Cohort 1) supported the null hypothesis that there are no differences in A1C, blood pressure and psychosocial stress between the two groups. Conversely, the analysis of pre-post-test changes in all those who received the Tai Chi intervention (Cohort 2) showed that A1C, diabetes-related distress and immigration-related stress significantly improved after 12 weeks.

A. A1C

These inconsistent results reflect those of the literature evaluating the effects of Tai Chi on glycemic levels. Previous reviews of the literature have reported a wide variety of rigor in Tai Chi

studies which has made it difficult to ascertain the effects of Tai Chi on different measures of health

(Lee et al., 2015; Wang et al., 2010). A recent meta-analysis of RCTs using Tai Chi in diabetes

summarizes the most rigorous data to date (Lee et al., 2015). Lee et al. compiled the evidence presented

by 15 randomized trials comparing Tai Chi to different modalities of control, and measured its

effectiveness in reducing A1C and fasting blood glucose. The meta-analysis failed to find positive

effects on A1C when Tai Chi was compared to different types of physical activity (dancing,

conventional exercise, walking). Comparing Tai Chi to anti-diabetic medications suggested positive

effects on fasting glucose but not on A1C. One randomized trial showed favorable effects on A1C and

fasting glucose when Tai Chi was used as a supplement to standard diabetes care compared to standard

diabetes care alone without medication (Youngwanichsetha, Phumdoung & Ingkathawornwong, 2013).

Comparing Tai Chi to a wait- list control did not show definitive results. In summary, the available

evidence so far is not compelling enough to confirm positive effects of Tai Chi on glycemia. There is

still need for more rigorous studies with larger sample sizes and with more standardized implementation

(Lee et al., 2015).

There is significant variation in the Tai Chi styles applied, the expertise of the instructor, and the

length and intensity of the intervention. Even among randomized trials, there is no consensus on a

standard format that could simplify comparisons. Several styles of Tai Chi are reported in the literature:

Yang, Wu, Sun, Cheng, and combinations of two or more of them (Lee et al., 2015; Li et al., 2005; Shen

et al., 2007; Tsang et al., 2008; Yeh et al., 2007). Yang is the most commonly reported but it's

implemented in different short and long forms. The long form of 108 movements it's rarely used; Yang

short form however, is frequently used in its 24 move version (Li et al., 2005; Shen et al., 2007), with

some studies implementing an even shorter version of 12 moves (Tsang et al., 2008). Little attention is

given to the experience and certification of the instructors, with few studies mentioning their

qualifications. This adds uncertainty to the quality of the instruction and the fidelity of the program in adhering to the traditional styles and forms.

The reported intensity of the intervention may vary from twice per week (Shen et al., 2007; Tsang et al., 2008) to three (Lo, Yeh, Chang, Sung, & Smith, 2012) to six (Li et al., 2001b; Pan, Zhang, & Tao, 2015) days per week, for periods of eight weeks (Lo et al., 2012) to six (Li et al., 2001a) to 12 months (Lee et al., 2015; Li et al., 2001b). As a type of physical activity, Tai Chi could be expected to demonstrate a dose effect in which more exposure may lead to better practice and hypothetically better outcomes. Thus, attending to the frequency and intensity of the practice becomes very important in establishing comparability among trials. Finally, Tai Chi twice a week for 12 weeks as implemented in my study seems to be at the lower end of the intensity and course length spectrum which could partially explain the negative results. Other studies with small samples but more intensive and longer intervention (Li et al., 2001b) have observed significant results.

The randomization process presented some difficulties. The two groups showed a significant difference in the number of insured participants, and differences on A1C levels and years of education that were close to significance. It is well known that lack of insurance and education are obstacles to self-care and indirectly affect A1C (Mutchler, Bacigalupe, Coppin, & Gottlieb, 2007), and in such a small sample these associations may have remained strong and difficult to overcome. With a higher level of A1C, the control group had more room for improvement, and presented a larger reduction in A1C than the Tai Chi group. This could be attributed to regression to the mean (Gilovich, 1991), or the randomization may have resulted in a very enthusiastic and motivated control group that presented an important Hawthorne effect.

Tai Chi is a stress management technique that incorporates a meditative and a physical activity component, and it is speculated that both aspects impact the stress process, possibly in differing ways

(Wayne & Kaptchuck, 2008). Diet, other types of exercise and stress reduction practices were factors potentially influencing the outcomes in unaccounted ways. Only two questions in the Summary of Diabetes Self-Care Activities Measure evaluated changes in the number of days the participant followed a general and a specific diet. These measures may have proven insufficient to identify potential changes in carbohydrate consumption that directly altered A1C levels. Future studies should refine the assessment of this important covariate by reporting more detailed nutrient consumption and potential changes throughout the study.

At enrollment, potential participants already engaged in exercise were asked about the regularity and intensity of their practice. A participant engaged in active regular or intense exercise was not considered eligible to enter the study. Two questions in the Summary of Diabetes Self-Care Activities Measure assessed the number of days per week the participant was engaged in general physical activity for more than 30 minutes in the day, and in a specific type of exercise like biking, tennis, etc. Unexpectedly, the number of days engaged in physical activity were positively correlated with A1C, which I believe it's an artifact since 30% (n=12) of the sample reported 0 days of physical activity at baseline. Besides detailed questionnaires, future studies could incorporate physiological markers of physical activity, assessing pulmonary capacity and physical function (Taylor-Piliae, 2008).

Other than prayer, the practice of different forms of stress reduction in the target population was expected to be very limited. At enrollment participants were asked about their stress reduction practices, and they did not report regular practice of yoga or meditation. I did not use an instrument to assess the use of prayer or other forms of relaxation, nor did I consider prayer a reason for exclusion. Since the majority of participants were recruited through their churches, I expected to find prayer similarly distributed among the treatment and control groups.

Encouragement and verbal persuasion from other participants and the instructor cultivate efficacy beliefs that facilitate behavioral change (Bandura, 1997). This is how social support could influence self-efficacy and in turn modify Tai Chi practice (Bandura, 1997; Li et al., 2001), indirectly influencing the primary outcomes. The scores did not show significant change in either of these two covariates, maybe due to a short intervention or to a Tai Chi practice that did not reach the recommended 150 minutes/week of physical activity (ADA, 2015). Future studies would benefit from continuing assessment of these two covariates.

Changes in medication throughout the course of the study could have been implicated in the changes in A1C from pre- to post-test (ADA, 2015). However, six participants reported increase while 6 others reported reduction in medication, one did not answer the question and the majority of the sample reported no changes. This information was collected as a categorical variable; no account of the dosages, number of pills or insulin injections was requested. It is possible that the information collected was insufficient or was disguising nuanced changes in treatment that could have impacted glycemic levels.

Medication adherence was expected to directly affect the levels of A1C, and a significant negative correlation was found between medication adherence and A1C at baseline in the Randomized Controlled Pilot. Insulin use was a significant predictor at baseline in this group, as well. From among those who provided both baseline and post-test information, 13 participants reported increase in adherence scores, 11 showed reductions, and 6 reported no change. In the aggregate, scores did not show any changes from pre- to post-test (5.97 ± 1.89 at pre-test vs. 5.968 ± 1.68 at post-test; p= 1.0).

Also, a large proportion of the sample had no medical insurance which constrained the possibility of changing type or dosage of medication. This information suggests that medication was not

the variable driving the changes in A1C, however small. Medication adherence also showed a significant negative correlation to Intra-familial stress and a positive correlation to low social support, suggesting that family dynamics and their associated support are an important influence in the medication part of diabetes self-care. These findings corroborate reports by Caban, Walker, Sanchez, and Mera (2008) and others (Rivera, 2003; Schoenberg et al., 2005).

The pre-post-test analyses of All Tai Chi participants found a significant reduction in A1C that can be compared to other two reports (Shen et al., 2007; Yeh et al., 2007). In their study with a single group, pre-post-test measures design, Yeh et al. evaluated the effect of a 12-week Tai Chi intervention on 39 patients with type 2 diabetes, and observed a significant reduction of 0.46% in A1C (p=0.026). My intervention differed from theirs in the frequency (two hours per week in mine vs. 3 hours in theirs), but observed a reduction of 0.28% in A1C that was significant at p=0.017. Shen et al. (2007) however did not see significant changes in A1C in their sample of 25 participants in their feasibility study. Their intervention had the same intensity and length than mine but their 1% decrease in A1C failed to reach significance. These inconsistencies in results illustrate the current state of the broader literature regarding Tai Chi and its effects on diabetes.

My study found that the time dedicated to practice of Tai Chi was a significant predictor of A1C values. Although not supported by the randomized pilot, this result strongly suggests that Tai Chi is a valid low intensity intervention that can yield significant clinical effects and its application and dissemination are warranted. These results support the findings by Hansen et al. (2009) and Mendonca et al. (2011) that low intensity exercise can have important physiological impact.

Recent studies call for the implementation of trials that address the methodological weaknesses already described above (Lee et al, 2015), and that address also the challenges to validity inherent to the implementation of Tai Chi as a "holistic" approach (Wayne & Kaptchuck, 2008). More attention should be given to establishing protocols that standardize modes of implementation, frequency and intensity of intervention, and qualifications of teachers/trainers to facilitate comparisons between studies by reducing risk of bias.

B. <u>Blood Pressure</u>

Blood pressure did not show significant change in either of the two sets of analyses. These results are in contradiction to those of several studies (Lo et al., 2012; Pan, Zhang, & Tao, 2015; Wang et al., 2013; Yeh et al. 2008). Lo et al. (2012) compared an 8-week intervention to usual care in a quasi-experimental study assessing the effects of Tai Chi on blood pressure. They found significant reduction in systolic and diastolic blood pressure. More recently, Pan, Zhang, and Tao (2015) conducted a clinical trial assessing the effect of Tai Chi on blood pressure levels and biochemical markers of cardiovascular health (nitric oxide, CO_2) in patients with essential hypertension, compared to a group of hypertensives receiving usual care, and a healthy control group. The intervention was conducted for 60 minutes, 6 days a week, for 12 weeks, and even though the sample size was small (N=56), Tai Chi significantly improved blood pressure and markers of its underlying mechanisms.

In general, systematic reviews conducted by Yeh et al. (2008) and Wang et al. (2013) show encouraging evidence of the effects of Tai Chi on blood pressure but the quality of the evidence is inconsistent. The review of the literature by Lee et al. (2010) for example, finds the evidence still limited. Most of the articles evaluated in these reviews show small sample sizes and have methodological problems. One salient deficiency is the lack of consistency in the protocol for the measurement of blood pressure (Wang et al., 2013; Yeh et al., 2008). Usually three measurements

should be taken on three different days and the average entered as the recorded value but this is usually not the procedure for all studies. This was not the procedure that was followed in the implementation of my study, since three consecutive days of measurements were not logistically feasible. This may have contributed to error and lack of results in my study.

C. **Diabetes-related Distress**

In my study, the relationship between diabetes distress and Tai Chi was not evident in the first set of analyses in the context of the randomized pilot. But in the secondary pre-post-test analyses, the relationship reached significance in the expected direction, which may be attributed to the larger sample size (N=41).

I could not account for current literature on diabetes-related distress and Tai Chi. But the relationship between diabetes-related distress and A1C has received some attention. Fisher, Glasgow, Mullan, Hessler, Arean, & Masharani (2010) found this relationship to be more significant than that of A1C to clinical depression or depressive symptoms in a non-interventional study of 506 patients with type 2 diabetes (Fisher et al., 2010). Patients were assessed at baseline, 9 and 18 months on these three emotional states (diabetes distress, clinical depression and depressive symptoms), demographics, self-management, stress and A1C. Multilevel modeling evaluated cross-sectional and time-varying relationships between A1C and the emotional states; and prospective relationships of the baseline variables to A1C and the emotional states.

Cross-sectional and time-concordant relationships between A1C and diabetes distress were statistically significant. No prospective relationships were found between those two variables, indicating no cause-effect relationship. The association between A1C and diabetes distress seems to be bi-directional and mediated by other variables, for example when diabetes distress affects self-care

behaviors which indirectly affect glycemic control, or when uncontrolled circumstances lead to poor glycemic control which generates distress in the patient (Fisher et al., 2010). Another study by Karlsen, Oftedal and Bru (2011) however, found that glycemic control is less important than perceived social support and coping styles in relation to diabetes distress. Self-blaming and behavioral disengagement are significantly related to emotional distress in patients with diabetes (Karlsen, Oftedal & Bru, 2011), but they do not necessarily translate into poor glycemic control.

Diabetes distress seems to reflect the impact of negative coping mechanisms or "non-constructive social interactions" and the patient's negative perception of his/her own self- management, regardless of whether glycemic levels are actually under control or not (Karlsen, Oftedal & Bru, 2011). Their recommendation is to approach diabetes distress with both psychosocial and biomedical interventions (Karlsen, Oftedal & Bru, 2011). In my study, perceived stress and low social support were found predictors of diabetes distress, results that are supported by the findings of Fisher et al. (2010) and Karlsen, Oftedal and Bru (2011). My study also attempted to address both recommended psychosocial and biomedical aspects by engaging in positive coping through physical activity, and by providing a positive social environment that facilitated disengaging from emotional/negative coping. The Tai Chi intervention, especially its exercise component and social interactions, may have "activated" the bi-directional relationship between diabetes distress and A1C that Fisher et al. (2010) describe, thereby reducing diabetes distress and positively impacting glycemic levels.

D. <u>Perceived Stress</u>

The perceived stress scale measures an individual's cognitive assessment of stressful situations (Cohen & Williamson, 1988). Stressful events occur when the individual perceives a threat to his/her well-being, when conditions are uncontrollable, overloaded or unpredictable (Cohen, Kamarck & Mermelstein, 1983; Cohen & Williamson, 1988). In the current study, no significant changes in

perceived stress were observed from baseline to post-test in either the randomized pilot or the pre-posttest analyses. Several articles have assessed the effects of Tai Chi on stress using PSS and other instruments. A meta-analysis of four randomized controlled trials and four non-randomized comparison trials with 444 participants by Wang et al. (2010) found that Tai Chi had statistically significant improvements in stress management and psychological distress. Two of the studies included had small sample sizes and still reported significant results.

Sun, Dosch, Gilmore, Pemberton, and Scarseth (1996) conducted a RCT to assess the effect of Tai Chi on 20 (10 per group) Hmong immigrants in the U.S. Participants received the intervention on a weekly 2-hour session, for 10 weeks. They assessed stress using subjective and objective measures that showed significant differences in perceived stress scores (p=.0002) and body temperature (p=.0018), respectively. Taylor-Piliae et al. (2006) used a non-comparison longitudinal study to evaluate the effects of Tai Chi on perceived stress levels in a group of 38 Chinese immigrants. The intervention was 60 minutes three times per week for 12 weeks using the Yang style 24-posture short form. In spite of their reported low stress levels (15.5 $\pm$6.9), researchers observed a continuous reduction in stress over 12 weeks (-2.5 $\pm$5.0) (p= 0.009). Researchers attributed the significant change to an underreporting of stress at baseline, reflecting Chinese cultural norms. The sample size (38 vs. 41) and the baseline values (15.5 $\pm$6.9 vs. 14.81 $\pm$7.4) were similar to my study, except they did observe significant changes. Important differences between the studies should be noted: the group of Chinese immigrants were familiar with the practice of Tai Chi in their home country and received the instruction in their own language. It's possible that these conditions in the Chinese group facilitated experiencing a higher level of self-efficacy than Hispanics could; also the intensity of the intervention was higher which could have influenced the results.

Qualitative studies have found that the major sources of stress for Hispanic/Latino women with diabetes are related to their families' demands and little personal attention to themselves (Caban et al., 2008; Caban & Walker, 2006; Hatcher & Whittemore, 2007). This experience reportedly changes after age 55 when the majority of the familial burdens ease out and the women may assume a less demanding role as grandmothers (Caban & Walker, 2006). It is possible that in the Hispanic/Latino cohorts constituted by a majority of women, the responses to the PSS reflect their experience at this time of their lives. This could also explain the strong correlation of perceived stress with intra-familial stress among immigrants, and the trend toward significance noted in the linear model with group by time interaction. It's also plausible that the stress scores may have reflected a lack of meaningful negative events during the course of the study, consistent with the low levels of perceived stress reported at baseline. Future studies should consider a longer or more intensive intervention, and objective assessments of stress such as salivary cortisol (Esch, Duckstein, Welke, & Braun, 2007; Jin, 1992).

E. Immigration-related Stress

The assessment of stress related to the experience of being a Hispanic/Latino immigrant covers aspects pertaining to family life, marital and parental stress (intra-familial stress) and those related to environmental stressors such as occupational, and immigration situations (extra-familial stress) (Cervantes et al., 1991). In the first set of analyses for the randomized pilot, there were no significant differences between the treatment and control groups in changes in immigration-related stress. However, in the set of pre-post-test analyses, changes in immigration-related stress were significant, carried mostly by a reduction in extra-familial stress. Extra-familial stress has been associated significantly with being male, young, unemployed, undocumented, separated from the nuclear family, being alone, lacking English proficiency, and particularly, fear of deportation (Arbona et al., 2010). Although lack of English proficiency and fear of deportation may be found in the current sample of immigrants participating in the Tai Chi study, the other characteristics are not. The immigrant subgroup in my study is older than

50, mostly female, has been in the U.S. for more than 10 years, retired or employed, and well connected to their nuclear family. Examining the scores of those responding to the questionnaire indicated that the majority of the extra-familial stress scores were low, with a small number of outliers shifting the values for the whole subgroup. Thus, the resulting significant effect should be viewed with caution because it may be due to the small sample size. I did not find literature on the relationship between immigration-related stress and Tai Chi. Future studies on larger samples of Hispanic/Latino immigrants should assess the effect of stress reduction practices on measures of immigration-related stress.

F. <u>Limitations</u>

Although this initial study of Tai Chi for Hispanic older adults offers encouraging results, important threats affect their validity. Even though a randomized controlled design should have eliminated selection bias as a threat to validity, two participants allocated to the control group self-selected into the treatment group. Randomization was conducted blindly and using an internet website. The original allocation yielded a non-significant difference between groups on levels of A1C, and health insurance (see Appendix K). After the two participants' self-assignment, the sample showed a significant difference between the Tai Chi and the control groups on levels of health insurance (p=.048), and statistical trends on levels of A1C (p=.056), and years of education (p=.08). In the control group the number of uninsured was twice as large as that of the treatment group.

These differences in health insurance coverage may have been associated with other unmeasured qualities of the groups like expectancy. For example, among Latinos with no coverage I have seen high receptivity to and participation in community health education programs (Castillo et al., 2010). The differential selection could give as a result, a control group highly responsive to routine experimental observation demonstrating a Hawthorne effect. To address this bias, I conducted intent-to-treat analyses using the original allocation of participants for an equal N in each group. Also, an assessment of

expectation could have helped explain to what extent the control group outcomes were the result of their intrinsic motivation. Future studies should assess expectancy and consider block randomization by health insurance status and/or years of education to avoid bias. For studies among Hispanic/Latinos it is likely that the advent of the Affordable Care Act will not reduce significantly the number of uninsured. So block randomization on the variables mentioned above will be well justified.

As mentioned above, A1C values in the treatment and control groups showed an almost significant difference of 0.89% (7.55 $\pm$1.2 vs. 8.44 $\pm$1.7, respectively; p=.056) at baseline.

This high value for the control group at baseline can be considered random error that sets up the conditions for a potentially large decrease at post-test because of the natural tendency of values to approach the mean in several measures (Gilovich, 1991). Since the control group did not receive treatment, this proposition is plausible if the other effects (selection bias, Hawthorne effect, etc.) were to be discarded. Using larger samples in future trials should reduce the probability of encountering this limitation.

Data collection had to be conducted in one single visit precluding the implementation of ideal protocols for blood pressure measurement that require assessments in three different days. Questionnaires assessing acceptability, barriers and facilitating factors for the practice of Tai Chi were developed using published data but were not validated instruments. All other instruments were validated and translated into Spanish. One questionnaire assessing the amount and intensity of physical activity was initially included among the instruments but the majority of participants considered that the questions did not apply to them. The questionnaire was excluded from analysis. Except for clinical markers (A1C, blood pressure, BMI) and attendance logs, assessments relied significantly on self-report, enhancing the probability of recall bias or responses tainted by social desirability which is documented

to affect the quality of responses among Hispanics (Hopwood, Flato, Ambwani, Garland & Morey, 2009; Warnecke, Johnson, Chavez, Sudman, O'Rourke, Lacey, et al., 1997).

Attrition was a little above 30% which represents that almost one third of the participants did not complete the program. This level of attrition is similar to other studies implemented in that community (Castillo et al., 2010), and likely due to several factors: the long wait between recruitment and the initiation of the intervention, conflicting commitments with family and/or work, and health limitations. Attrition is a well-known problem for the implementation of health education and/or physical activity interventions in community settings (Castillo et al., 2010). As mentioned previously, I incorporated participants' recommendations in the design and implementation of the intervention in order to maximize retention; during the course of the study I contacted by phone the participants who had missed a session, provided encouragement to maintain attendance, and offered transportation to those who would need it.

Those who withdrew from the study did not differ significantly from the completers in age (p=0.75); education (p=0.23); years since diabetes diagnosis (p=0.95); A1C (p= 0.097), systolic blood pressure (p=0.47); diastolic blood pressure (p=0.67); perceived stress (p= 0.28); diabetes distress (p=0.99); intra/extra-familial stress (0.49); physical activity self-efficacy (p= 0.62); social support (p=0.94); diet (p= 0.29), or exercise (p=0.76).

In their feasibility study with a community sample, Shen et al. (2007) reported similar obstacles to attendance but a much larger attrition rate of 48%. The reasons for attrition in their sample are consistent with those reported by the participants in my study.

In regards to the effects on external validity, there is a risk of limited generalizability due to the Hawthorne phenomenon and experimenter bias. The Hawthorne effect refers to the behavioral change that takes place when the individual knows that is being observed. Although not intended, the control group seemed to be very active as demonstrated by an almost significant difference in A1C between baseline and post-test values, with a mean reduction of $0.336\% \pm 0.59$; p=.054. This group received health information once a month in discussions covering dietary recommendations that could have triggered unreported behavioral modifications. Although participants were advised to maintain their regular routines, the attention time given to the control group was a lot less than that received by the treatment group, and no consistent monitoring of their physical activity or diet routines were implemented. It is possible that the recommendations received regarding health and well-being was followed with more discipline and enthusiasm than expected. These behavioral changes were unreported at post-test evaluation.

Due to staffing constrains, the majority of data collection was conducted by the principal investigator. Usually a group of participants received the questionnaire and verbal instructions on how to complete it. While they answered the questionnaires, I assessed weight, height, blood pressure and A1C. Most of the participants were able to understand and respond to the questions on their own. But due to literacy problems or poor vision it was necessary to conduct individual interviews for some of the participants. This differential approach increased the risk of experimenter bias in the interviewer, and may have increased social desirability in the interviewee.

According to the nascent field of whole systems research, Tai Chi and other integrative health methodologies (yoga, meditation, etc.) should be approached using an ecologic framework that deals with complex systems and multivariate phenomena (Wayne & Kaptchuck, 2008). Because these practices combine multiple components (movement, imagery, visualization, breathing, etc.) that

contribute to the final effect of the technique, their components cannot and should not be evaluated separately. Therefore, the current placebo-controlled trials and randomization methods represent a very reductionistic approach that tries to isolate the "active ingredient" with disregard to the interdependence of all the components. In particular, Tai Chi requires attention, imagery and visualization as parts of the execution of the movements.

Removing "non-specific" elements such as attention or visualization changes the nature of the activity and invalidates the intervention (Wayne & Kaptchuck, 2008). Also, the practice of Tai Chi requires the intention and expectation of a positive outcome. In randomization, an individual with no interest to engage in the practice who is assigned to the Tai Chi intervention could actually create bias (Verhoef, Lewith, Ritenbaugh, Boon, Fleishman & Leis., 2005).

The results of clinical trials may be due to multiple components inherent to the technique that are not being measured but that are affecting body systems in significant ways to provide the results observed (Wayne, Krebs, Wolf, Gill-Body, Scarborough, McGibbon, et al., 2004). These arguments question the conclusions drawn from the current literature and my own study. In my pilot there were no attempts to measure attention, visualization or breathing. And while participants simply were instructed to attend to their breathing and to imagine peaceful surroundings, the priority was still given to the movements. It is possible that insufficient emphasis was given to critical aspects of the Tai Chi practice that could have ensured better results (imagery, cognitive), or that the instruments used in the evaluation or the length of the study did not allow capturing more nuanced transformations that could have taken place during the intervention.

Other general issues that may have also affected the outcomes include the small sample size, and the budget restrictions. The target sample of 70 (35 per group) could not be reached due the slow

enrollment of participants and delayed initiation of intervention that conflicted with contract deadlines, hence reducing the recruitment period. A sample size smaller than originally estimated, limited the probability of finding significant differences in treatment and control group comparisons. Budget restrictions made it unfeasible to hire a larger number of recruiters or data collection staff to speed up the process and limit bias.

G. Implications for Research and Practice

The research literature on Tai Chi has grown significantly in the last few years. Multiple studies report positive results in the use of Tai Chi for arthritis, hypertension, diabetes, psychological trauma, immunological disorders, cancer, HIV and more. The breath of the areas of inquiry and the potential applications are enormous, and the literature is populated by studies addressing interesting questions, with more rigorous methodologies and larger sample sizes. The first meta-analyses (Lee et al., 2015; Wang, Bannurum, Ramel, Kupelick, Scott & Schmid, 2010; Wang, Feng, Yang, Liu, Teng, & Xiong, 2013) on the effects of Tai Chi on psychosocial status, hypertension and diabetes are relatively recent suggesting a broad future for research in multiple areas of health from primary to tertiary prevention.

Future research should focus on refining the methodology of Tai Chi research by conducting randomized trials that address the shortcomings of the current and other pilot studies reported in those meta-analyses (Lee et al., 2015; Wang, et al., 2010; Wang, et al., 2013). The use of larger samples will clarify the associations among variables suggested by underpowered studies. Researchers should also consider the standardization of the Tai Chi style to be applied (Yang in a relatively short form that can be easily taught and learned by older adults), and consistently use an implementation format than can facilitate comparisons for more reliable outcomes from meta-analyses. Newer studies should consider increasing intensity of the practice (> 2 times per week), and/or length of the intervention (> 3 months) to allow ample time for incorporation of all elements of the Tai Chi practice (breathing, visualization,

etc.) and for the potential physiological and psychological changes to manifest. The standardization of the frequency, length and style of the intervention will facilitate comparisons between trials and define the effective "dosage" of the intervention that will provide clinical effects.

Tai Chi should be evaluated in contrast with other mind-body practices such as meditation, yoga and mindfulness in their capacity to enhance the quality of life and biomedical conditions of practitioners. The use of newer analytical tools like path analysis, structural equation modeling (Bell, Caspi, Schwartz, Grant, Gaudet, Rychener, et al., 2002) and latent growth curve analysis (Li et al., 2001a), suggested for the assessment of whole systems research should be encouraged.

The results of the current pilot study suggest potential benefits of Tai Chi on the mental and physical well-being of Hispanic/Latino older adults with diabetes. Research should expand on the effects of Tai Chi on glycemic levels, diabetes distress and acculturation stress. Studies with larger samples may add to the body of literature that has found a positive effect of Tai Chi on glycemic levels (Liu et al., 2009; Tsang et al., 2008; Yeh et al., 2007), may explore more thoroughly the impact on diabetes distress to enhance the patient's involvement in self- management; evaluate the role of Tai Chi in alleviating the fear and instability of immigrants, and elucidate the role of moderating factors such as social support and self-efficacy. New research should seek to identify the distinct contributions of Tai Chi as a type of physical activity and stress reduction technique for Hispanic/Latino patients with and without diabetes, compare the different aging subgroups (younger old, older old, and oldest old) on the receptivity and effectiveness of the technique, and uncover specific conditions for best practice for each age group.

Finally, Tai Chi can be easily implemented in community settings and has a potential to address the need for sustainable programs in public health. As a form of physical activity (Taylor-Piliae &

Froelicher, 2004), Tai Chi has shown to be a safe, viable alternative to more strenuous forms of physical activity for frail, sedentary or unconditioned populations, and for some with physical limitations. The use of an instructor that verbally describes while physically demonstrates the movements and the need for repetition serve to address potential learning limitations in the training of older adults (Purdie & McCrindle, 2002). In the absence of an instructor, there are affordable good programs in video format. Because Tai Chi does not require any equipment, it is a low cost behavioral intervention that can be practiced indoors or outdoors at the individual's convenience. It can be implemented individually or in groups, and offers an opportunity for the delivery of high quality population-based wellness and prevention services.

In conclusion, Tai Chi is a multi-component strategy to enhance well- being and health that has been used for centuries in different populations. In this pilot study I applied this technique to assess its feasibility, acceptability and potential health benefits on a group of Hispanic/Latino older adults from South Chicago. In spite of multiple methodological shortcomings affecting the randomized pilot study, the pre-post-test results on a sample of 41 participants showed significant reductions on levels of A1C, diabetes distress and acculturative stress. These findings call for further evaluations with larger samples and new research methodologies. The current state of the field proposes the evaluation of multi-component interventions like Tai Chi applying whole systems research and multivariate analytical tools. Tai Chi holds promise as a low cost, effective strategy to improve well-being among Hispanic/Latino older adults with type 2 diabetes.

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APPENDICES

APPENDIX A

UIC UNIVERSITY OF ILLINOIS AT CHICAGO

¿Do you have diabetes?

If so, we need you to participate in a research study about exercise, stress and diabetes!

You may be eligible to participate in this study if you:

- **Are between 50 and 80 years of age,**
- **Have been diagnosed by a doctor with type 2 diabetes,**
- **Are Hispanic/Latino,**
- **Can do physical activity, and**
- **Will not be traveling during the next 6 months.**

The study compares Tai Chi, a different kind of physical activity, to health and exercise advice to see if it helps you reduce blood sugar levels and stress.

If you are eligible, you will be asked to participate in physical activity classes twice a week for 12 weeks, either at the beginning of the study or after 3 months. Classes will last 1 hour and will be at no cost to you. *You will be compensated for answering some questionnaires.*

Please, call Centro Comunitario Juan Diego at 773-731-0109, or call 312-996-0683, or send an e-mail to amparo@uic.edu if you want to learn more about this study and to determine your eligibility.

This research is conducted by Dr. Amparo Castillo at the University of Illinois at Chicago (1747 W. Roosevelt Rd, Room 555, Chicago, IL 60608; e-mail: amparo@uic.edu).

Flyer-- version 3- 8/06/12

UIC UNIVERSITY OF ILLINOIS
AT CHICAGO

¿Tiene usted diabetes?

*¡Si es así, lo necesitamos para tomar parte en un
estudio de investigación sobre el ejercicio,
el estrés y la diabetes!*

**Usted puede ser elegible para participar
en este estudio si usted:**

- **Tiene entre 50 y 80 años de edad,**
- **Ha sido diagnosticado por un médico con diabetes tipo 2,**
- **Es Hispano/Latino,**
- **Puede hacer actividad física, y**
- **No estará viajando durante los próximos 6 meses.**

**Este estudio se realiza para comparar Tai Chi, una forma distinta de
actividad física, con recomendaciones sobre salud y ejercicio, y ver si
puede reducirle los niveles de azúcar en la sangre y el estrés.**

**Si usted es seleccionado(a), se le pedirá participar en clases de actividad
física dos veces por semana por 12 semanas, ya sea al principio del
estudio o al final. Las clases durarán 1 hora y son** gratis**.**

Usted será recompensado por contestar unos cuestionarios.

Si está interesado, por favor llame a Centro Comunitario Juan Diego al 773-731-0109 o
al 312-996-0683, o envíe una nota a amparo@uic.edu para informarse más acerca de este
estudio y ver si es elegible.

Esta investigación es realizada por la Dra. Amparo Castillo de la Universidad de Illinois
en Chicago (1747 W. Roosevelt Rd, Chicago, IL 60608; correo electrónico:
amparo@uic.edu).

Flyer --version 3- 8/06/12

APPENDIX A (continued)

<u>Stress Reduction for Elderly Hispanics Study</u>

<u>Recruitment Script- English Version</u>

Thank you for allowing me today to talk about a research study that is being conducted by the University of Illinois at Chicago. Studies have demonstrated that older persons with type 2 diabetes can benefit when they participate in exercise or stress reduction programs.

Currently we are conducting research with Hispanic/Latino older adults, to study a type of exercise program that has been found effective for diabetes, Tai Chi. We are looking for Hispanic/Latinos between 50 and 80 years of age, who can exercise, and who will not be traveling during the next six months, to be enrolled in the study. Participants will be selected by chance to either take the classes at the beginning of the study or after a 3-month waiting period. The Tai Chi classes will be twice a week for 12 weeks, at no cost, and will last 1 hour. Participants will receive compensation for checking their blood sugar and stress levels, and for answering questionnaires. The study will last 6 months, and all participants will receive the Tai Chi classes. Do you have any questions about the information presented?

<u>Screening script:</u>

To participate in the study, persons need to be Hispanic/Latino, older adults and have diabetes. They should be able to exercise on their feet, and not be practicing other relaxation methods. If you are interested, we will need to ask you some questions to determine if you are eligible to participate. These questions will be about your diabetes and the complications you may have because of diabetes. We will also ask you for contact information like phone number or e-mail address, in order to contact you to inform you the time and place of the meetings to measure your blood sugar, your blood pressure and your weight, and to answer the questionnaires. Will you agree to provide this information to find out if you are eligible for the study?

APPENDIX A (continued)

<u>Stress Reduction for Elderly Hispanics Study</u>

<u>Recruitment Script- Spanish Version</u>

Gracias por permitirme hablarles hoy acerca de un estudio de investigación que la Universidad de Illinois en Chicago está realizando. Estudios han demostrado que personas mayores de edad con diabetes tipo 2, pueden beneficiarse cuando participan en programas de ejercicio o de reducción de estrés. Actualmente estamos investigando un tipo de actividad física que ha demostrado ser efectivo para reducir la diabetes y el estrés: Tai Chi. Buscamos hispanos entre los 50 y 80 años de edad, que puedan hacer ejercicio y que no vayan a viajar durante los próximos 6 meses. Cada participante será asignado al azar para tomar las clases al principio del estudio o después de un periodo de espera de 3 meses. Las clases de Tai Chi serán dos veces por semana por 12 semanas, sin costo, y durarán 1 hora. Los participantes recibirán compensación por medirse el azúcar y contestar cuestionarios. El estudio dura 6 meses y todos los participantes recibirán las clases de Tai Chi. Tiene alguna pregunta?

<u>Screening script:</u>

Para participar en la investigación, las personas deben ser hispano/latinos de la tercera edad, y tener diabetes tipo 2. Estas personas deben ser capaces de hacer ejercicios de pie, y no estar practicando otro método de relajación. Si usted está interesado/a, nosotros necesitamos hacerle algunas preguntas para determinar si es elegible. Estas preguntas son acerca de su diabetes y de las complicaciones que puede haberle causado. También le pediremos información personal como su número de teléfono o su correo electrónico, para poderle comunicar el lugar, día y hora de la reunión para medir su azúcar, su presión arterial y su peso, y para contestar los cuestionarios. ¿Está de acuerdo en dar esta información para averiguar si puede participar en el estudio?

APPENDIX A (continued)

Newsletter Blurb- English version

The University of Illinois at Chicago is conducting research studying a kind of physical activity that has proven to be effective for diabetes and stress reduction, Tai Chi. We are seeking Hispanic/Latino older adults with type 2 diabetes, between 50 and 80 years of age who can engage in physical activity and who will not be traveling during the next 6 months, to be enrolled in the study. Potential participants will get their blood sugar checked twice, and will answer several questionnaires. Candidates will be selected by chance to either take the classes at the beginning of the study or after a 3-month waiting period. Tai Chi classes will last 1-hour, and will take place twice a week for 3 months. The classes will have no cost, and participants will receive compensation for checking their blood sugar and answering the questionnaires. If you are interested, please call Centro Comunitario Juan Diego at 773-731-0109, or contact Amparo Castillo from the University of Illinois at Chicago at 312-996-0683, or send an e-mail to amparo@uic.edu, to learn more about the study and to determine your eligibility.

APPENDIX A (continued)

Newsletter Blurb- Spanish version

La Universidad de Illinois en Chicago, está investigando un tipo de actividad física que ha demostrado ser efectivo para reducir la diabetes y el estrés, Tai Chi. Estamos buscando latinos/hispanos de la tercera edad con diabetes tipo 2, entre los 50 y los 80 años de edad, que puedan hacer ejercicio y que no vayan a viajar durante los próximos 6 meses para que participen en este estudio. A aquellos que cumplan con los requisitos, se les medirá el azúcar en la sangre dos veces y contestarán varios cuestionarios. Los candidatos serán seleccionados al azar para tomar las clases al principio del estudio, o después de un período de espera de tres meses. Las clases de Tai Chi tendrán 1 hora de duración, dos veces por semana, por 3 meses. Las clases no tendrán costo alguno y los participantes serán recompensados por medirse el azúcar y contestar los cuestionarios. Si está interesado, por favor llame al Centro Comunitario Juan Diego al 773-731-010, o llame a Amparo Castillo de la Universidad de Illinois en Chicago al 312-996-0683, o envíe un correo electrónico a amparo@uic.edu para informarse más acerca del estudio y determinar si es elegible.

APPENDIX A (continued)

Date: _____

Dear Client:

You are invited to participate in a wonderful opportunity to do exercise and reduce your blood sugar levels!

The **University of Illinois at Chicago** in collaboration with **Chicago Family Health Center**, is conducting the **STRESS REDUCTION FOR ELDERLY HISPANICS STUDY** that tests a kind of physical activity that has been effective for diabetes and stress reduction: Tai Chi.

We are seeking Hispanic/Latino older adults with type 2 diabetes between 50 and 80 years of age who can engage in physical activity and who will not be traveling during the next 6 months, to be enrolled in the study.

Potential participants will get their blood sugar checked twice, will answer several questionnaires and will be selected by chance to start Tai Chi classes at the beginning of the study or after a 3-month waiting period. Tai Chi classes will last 1-hour, and will take place twice a week for 3 months. The classes will have no cost, and participants will receive compensation for checking their blood sugar and answering the questionnaires.

If you want to know if you are eligible, or just want to learn more about the study, **please contact us**.

For more information:

- Come to **Chicago Family Health Center** and register your name and phone number at the front desk; or
- Call **Centro Comunitario Juan Diego** at **773-731-0109**; or
- Call **Amparo Castillo** from the University of Illinois at Chicago at **312-996-0683**; or
- Send an e-mail to amparo@uic.edu.

   We look forward to helping you improve your health and enjoy exercise!

Fecha:

Apreciado(a) Cliente:

Usted está cordialmente invitado/a a participar en una gran oportunidad de hacer ejercicio en grupo y reducir sus niveles de azúcar en sangre.

La **Universidad de Illinois en Chicago** en colaboración con **Chicago Family Health Center**, está realizando el **Estudio de Reducción del Estrés en Hispanos de la Tercera Edad** que investiga un tipo de actividad física que ha reducido la diabetes y el estrés: Tai Chi.

Estamos buscando latinos/hispanos de la tercera edad con diabetes tipo 2, entre los 50 y los 80 años de edad, que puedan hacer ejercicio y que no vayan a viajar durante los próximos 6 meses, para que participen en este estudio.

A aquellos que cumplan con los requisitos, se les medirá el azúcar en la sangre dos veces, y contestarán varios cuestionarios. Los candidatos serán seleccionados al azar para tomar las clases al principio del estudio, o después de un período de espera de tres meses. Las clases de Tai Chi tendrán 1 hora de duración, dos veces por semana, por 3 meses. Las clases no tendrán costo alguno y los participantes serán recompensados por medirse el azúcar y contestar los cuestionarios.

Si desea saber si es elegible, o si solo desea saber más sobre el estudio, por favor, **póngase en contacto con nosotros**.

Para mayor información:
- Venga a **Chicago Family Health Center** y registre su nombre y teléfono en la recepción;
- Llame al **Centro Comunitario Juan Diego** al **773-731-0109**; o
- Llame a **Amparo Castillo** de la Universidad de Illinois en Chicago al **312-996-0683**; o
- Envíe un correo electrónico a amparo@uic.edu.

¡Esperamos ayudarle a disfrutar del ejercicio y de una buena salud!
APPENDIX B

STRESS REDUCTION FOR ELDERLY HISPANICS STUDY (StREHS)
INITIAL SCREENING FORM

Name:		Screening #: S_____	ID#:
Cell Phone #:	Home phone #:		
Address:			
Age:	Sex: □ Male □ Female		

Inclusion Criteria **Does the patient meet any of the following criteria?**	**Yes**	**No**
Hispanic/Latino		
50 to 80 years old		
Diabetes type 2		
You were prescribed medications for diabetes		

Exclusion Criteria **Does the patient meet any of the following criteria?**	**Yes**	**No**
Visual impairments with inability to read		
Dialysis or diagnosis of end stage renal disease		
Severe neuropathy		
Amputations, foot ulcers/lesions		
Coronary heart disease or stroke		
Substance abuse		
Cancer		
HIV		
Planning to travel within the following 4 months		
Disoriented, confused, slurred speech		
Practicing formal exercise		
Trained in Tai Chi, yoga, relaxation, etc.		

Interested in the Study?	**Yes**	**No**
If no, reason why_____ _____		

Eligible ?   □ **Yes**   □ **Maybe**   □ **No**
If **Yes** or **Maybe**, invite to the second screening meeting.
How did you hear about the Study? □ Flyer   □ Poster   □ Radio   □ Doctor/health care provider   □ Newspaper   □ Other

APPENDIX B (continued)

STRESS REDUCTION FOR ELDERLY HISPANICS STUDY (StREHS)

INITIAL SCREENING FORM

Nombre:		Screening #: S_____	ID#:
Tel. Celular:	Tel. Casa:		
Dirección:			
Edad:	Sexo: □ Masculino □ Femenino		

Inclusión **¿Cumple el participante con estos requisitos?**	**Sí**	**No**
Hispano/Latino		
50 a 80 años de edad		
Diabetes tipo 2		
Se le ha recetado medicina para la diabetes		
Exclusión **¿Tiene el participante alguno de estos problemas?**	**Sí**	**No**
Impedimento visual con incapacidad para leer		
Diálisis o diagnóstico de enfermedad renal crónica		
Neuropatía severa		
Amputaciones		
Enfermedad coronaria		
Accidente cerebrovascular		
Úlceras o lesions en los pies		
Abuso de drogas		
Planea viajar en los próximos 4 meses		
Desorientado, incoherente y dificultad para hablar		
Practica ejercicio regularmente		
Recibió entrenamiento en Tai Chi, yoga, relajación		
Interesado en el 133tudio?	**Sí**	**No**

Si **No**, por qué?_____

_____

Elegible ¿	**□ Sí**	**□ Tal vez**	**□ No**

Si marcó **Sí** o **Tal vez**, invite a la segunda reunión de evaluación.

Como se enteró del estudio?	□ Volante	□ Poster	□ Radio
□ Doctor/proveedor de salud	□ Periódico	□ Otro	

APPENDIX B (continued)

STRESS REDUCTION FOR ELDERLY HISPANICS STUDY (StREHS)
SECOND SCREENING FORM

The following questionnaire serves to identify those patients with risk of complications. Potential participants should answer NO to these questions. When the answer is YES, follow the recommendations.

1. Do you have pain, tightness or pressure in your chest during physical activity (walking, climbing stairs, household chores, similar activities)?	**SI**	**NO**

Recommendation:
If person answered YES to this question and this is a NEW problem, ask them to see their health care provider first before starting any exercises. They should ask their health care provider "Are there any exercises that I cannot do"? Give participant a Letter to Healthcare Providers that describes the research study.
If it is not new, or has already been evaluated, they are eligible.

2. Do you currently experience dizziness or lightheadedness?	**SI**	**NO**

Recommendation:
If person answered YES, it is recommended that they talk with their health care provider before entering the study. They should ask if there are any exercises they cannot do. Give participant a Letter to Healthcare Providers describing the study.

3. Have you ever been told you have high blood pressure?	**SI**	**NO**

Recommendation:
Whether they have had their blood pressure checked or not within the last 6 months, measure their blood pressure with sphygmomanometer three times and calculate the average of the three measurements. If their blood pressure is at or below 160/90 mm Hg, they can continue in the study.
If their blood pressure is above 160/90 mm Hg, they should see a healthcare provider. Give participant a Letter to Healthcare Providers describing the study.

4. Do you have pain, stiffness or swelling in joints that limits or prevents you from doing what you want or need to do?	**SI**	**NO**

Recommendation:
If they answered YES, they can exercise to prevent worsening of arthritis and help manage their pain. If they have osteoporosis they should always avoid stretches that flex the spine or cause them to bend at the waist, and avoid making jerky, rapid movements. Tai Chi and low intensity exercises are not contraindicated in these cases.

APPENDIX B (continued)

5. Do you fall, feel unsteady, or use an assistive device while standing or walking?	**SI**	**NO**

Recommendation:
If they answered YES to this question, they will be excluded as these conditions are part of our exclusion criteria. See Initial Screening.

6. Is there a health reason not mentioned why you would be concerned about starting an exercise program?	**SI**	**NO**

R**ecommendation:**
If they answered YES to this question, encourage them to share this information with their doctor. If there is a serious co-morbid condition that was overlooked in the pre-screening questionnaire (cancer, HIV, stroke, etc.), the person should be excluded. If they need more information about the program, explain the nature of the exercises involved and ask them to get their healthcare provider's advice. Give participant a Letter to Healthcare Providers describing the study.

APPENDIX B (continued)

STRESS REDUCTION FOR ELDERLY HISPANICS STUDY (StREHS)
SECOND SCREENING FORM-SPANISH

El siguiente cuestionario sirve para identificar aquellas personas con riesgo de complicaciones. Los participantes deberán contestar NO a esta preguntas. Cuando la respuesta sea SI, siga las recomendaciones.

1. ¿Tiene usted dolor u opresión en el pecho cuando hace actividad física (caminar, subir escaleras, hacer quehaceres domésticos, o actividades similares)?	**SI**	**NO**

Recomendación:
Si la persona contesta **SI** a esta pregunta y este es un problema **NUEVO**, pídale que visite a su proveedor de salud antes de empezar cualquier ejercicio. El/ella deberá preguntarle a su proveedor "¿Hay algún ejercicio que no puedo hacer?" Entréguele al paciente una copia de la Carta para el Proveedor de Salud que describe el estudio de investigación.
Si no es nuevo, o si ya ha sido evaluado, entonces el paciente es elegible.

2. ¿Siente actualmente mareo y/o borrachera?	**SI**	**NO**

Recomendación:
Si la persona contesta **SI**, es recomendable que hable con su proveedor de salud antes de iniciar el estudio. Deberá preguntarle si hay algún tipo de ejercicios que no deba hacer. Entréguele al participante una Carta para el Proveedor de Salud que describe el estudio.

3. ¿ Le han dicho que tiene la presión arterial alta?	**SI**	**NO**

Recomendación:
Aunque le hayan revisado la presión arterial en los últimos 6 meses, tómele la presión arterial con el esfigmomanómetro tres veces seguidas y calcule el promedio de las tres medidas. Si la presión está en 160/90 mm Hg o por debajo, puede continuar en el estudio.
Si está por encima, deberá ver a su proveedor de salud. Entréguele la Carta para el Proveedor de Salud que describe el estudio.

4. ¿Siente dolor, entumecimiento o hinchazón en las articulaciones que le limite o impida hacer lo que desea o necesita hacer?	**SI**	**NO**

Recomendación:
Si contesta **SI**, puede hacer ejercicio para prevenir el empeoramiento de la artritis y ayudar a manejar el dolor. Si tiene osteoporosis, deberá evitar estiramientos que flexionan la columna o la doblan en la cintura, y evitar movimientos bruscos y rápidos. Tai Chi y ejercicios de baja intensidad no están contraindicados en estos casos.

APPENDIX B (continued)

5. ¿Se cae, se siente desbalanceado, o necesita bastón o aparatos para mantenerse de pie o caminar?	**SI**	**NO**

Recomendación:
Si la persona contesta **SI**, deberá ser excluida ya que estas condiciones hacen parte de los criterios de exclusión descritas anteriormente.

6. ¿Hay alguna razón de salud que no haya mencionado antes por la que deba preocuparse si va a empezar un programa de ejercicios?	**SI**	**NO**

Recomendación:
Si la persona contesta **SI** a esta pregunta, recomiéndele que comparta esta información con su proveedor de salud. Si hay una condición de salud seria que se paso por alto en el primer cuestionario (cáncer, HIV, accidente cerebro-vascular, etc.), la persona deberá ser excluida. Si la persona necesita mayor información acerca del proyecto, explique la naturaleza de los ejercicios incluidos y pídales que obtengan el consejo de su proveedor de salud. Entréguele al paciente una Carta para Proveedor de Salud que describe el estudio.

APPENDIX B (continued)

UIC University of Illinois at Chicago

Date: _____

Dear Dr. _____

Your patient _____ has expressed interest in participating in the Stress Reduction for Elderly Hispanics Study funded by the National Institutes on Aging through the Midwest Roybal Center for Health Promotion and Translation at the University of Illinois at Chicago.

The study examines the effects of low intensity physical activity with Tai Chi on diabetes and psychosocial stress among Hispanic older adults. All potential participants are undergoing a screening process to ensure their medical status does not contraindicate their practice of exercise. We are requesting that you provide your patient with medical clearance for enrollment in the study.

Your patient will participate in classes of Tai Chi - Yang short form either at the beginning of the study or after a 3-month waiting period. Classes will be twice a week for 12 weeks, and will last 1 hour. Those who receive Tai Chi instruction at the beginning will be followed-up 3 months after the end of their instruction to assess their maintenance of exercise. Those in the waiting group will receive printed information about diabetes care, stress reduction and exercise for 12 weeks, and then will cross-over to take the Tai Chi classes for other 12 weeks. Both groups will receive instruction from a certified professional, and all precautions are taken to ensure a safe, comfortable and pleasant experience for all participants. Classes will take place at two venues in the community: Chicago Family Health Center and Victory Center.

If you have any questions or concerns regarding your patient's participation in the study, please feel free to contact us at 312-996-0683. Thank you for your support of our research project.

Sincerely,

Amparo Castillo, MD, PhD(c)
Principal Investigator
School of Public Health
Institute for Health Research and Policy
University of Illinois at Chicago
312-996-0683
amparo@uic.edu

| To signal your approval of your patient's participation in this study, please sign below. |
| Name: _____ |
| Signature: _____ |
| Date: _____ |

APPENDIX C

University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research
STRESS REDUCTION WITH TAI CHI FOR ELDERLY HISPANICS
WITH DIABETES

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator: Amparo Castillo, MD
Department: Institute for Health Research and Policy
Address and Contact Information: 1747 West Roosevelt Road – 5th Floor; 312-996-0683.
Funds for this study are provided by the National Institute on Aging from the National Institutes of Health, through the Midwest Roybal Center for Health Promotion and Translation at the University of Illinois at Chicago.

Why am I being asked?

You are being asked to participate in a research study that tests a modality of physical activity on its effectiveness to reduce levels of blood sugar, psychosocial stress and blood pressure. The study compares the traditional Chinese practice of Tai Chi with health and exercise advice among Hispanic/Latino older adults with type 2 diabetes.

You have been asked to participate in the research because you have identified yourself as a Hispanic/Latino(a), between 50 and 80 years of age, you are diagnosed with type 2 diabetes, do not have significant complications or health conditions that may interfere with the practice of exercise; you are not practicing exercise regularly, you will not be traveling out of town during the next 6months, you have not received previous training in relaxation therapies, yoga or Tai Chi; and you are willing to sign an informed consent.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 70 subjects from the Southeast Chicago community may be involved in this research at UIC.

What is the purpose of this research?

The study is being done to test if Tai Chi can reduce A1C, stress and blood pressure in Hispanic/Latino older adults with type 2 diabetes, compared to advice on exercise and healthy behaviors. Research has found that stress increases blood pressure and blood sugar levels; Hispanic/Latino older adults experience many stressors and there are no programs teaching them stress reduction or stress management. Tai Chi is a traditional Chinese form of exercise and meditation technique that reduces blood pressure and blood sugar levels and improves the quality of life of many older adults. There are no studies of Tai Chi with Hispanic/Latinos. This study finds out also what receptivity Hispanic/Latino

APPENDIX C (continued)

older adults may have for Tai Chi. The advice on exercise and healthy behaviors will be delivered to participants through brochures and pamphlets sent by mail and providing sound information on how to take care of diabetes, including diet tips and exercise recommendations

What procedures are involved?

This research will be conducted in Southeast Chicago in different venues. Classes will take place at the 2nd floor solarium at Chicago Family Health Center and at Victory Center..

You will need to come to the study site for 26 times over the course of 6 months. These will include 2 visits for the initial and final assessments that will last 2 hours each, and 24 visits for the 1-hour exercise classes that will be conducted twice a week for 12 weeks.

Four assessments will be conducted throughout the study. Two full assessments will include measurement of blood sugar, blood pressure, weight, and questionnaires. Two assessments will be short questionnaires to be conducted in person or over the phone. Once you have agreed to participate in the study and you have signed this consent form, you will undergo the initial assessment. In this assessment you will provide a drop of blood to measure your A1C; we will measure your height, weight and blood pressure, and you will answer a written questionnaire. This assessment may take 2 hours of your time.

After that, you will be assigned by chance to one of the two groups. You will not be able to choose your group. Your selection to one group or another will be done like tossing a coin.

One group will receive instruction in Tai Chi right after the initial assessment; the other group will initially receive health and exercise advice that they are free to follow, but then will receive instruction in Tai Chi after a waiting period of about 12 weeks. Classes for both groups will be led by a certified bilingual instructor. You will participate in the classes twice a week, for 12 weeks. Classes will last 1 hour. Each class may have up to 18 participants. You will be asked to practice at home every day for at least 5 minutes.

At week 6 into the study, participants in the Tai Chi group, will answer a short questionnaire (less than 5 minutes) about their experience practicing the Tai Chi exercises, and what makes it easy or difficult for them to do it, and how many minutes per day have they been practicing.

At the end of the 12 weeks both groups those receiving Tai Chi and those receiving health advice, will have the post-test full assessment in which they will answer another questionnaire and have their A1C, blood pressure and weight measured again. This assessment again, may take 2 hours of your time.

After this post-test assessment, the health/exercise advice group will cross over and receive the Tai Chi instruction. The classes will be exactly like those given to the first group, 1-hour sessions twice a week for 12 weeks. At week 6 of the instruction, participants will be asked to answer the short follow-up questionnaire. At the end of 12 weeks of instruction in Tai Chi this group will have another full posttest assessment including a second posttest questionnaire and measurements of A1C, blood pressure and weight. This evaluation will also last 2 hours.

APPENDIX C (continued)

Meanwhile, the group that originally completed the Tai Chi instruction will be expected to practice at home for 12 more weeks. At the end of those 12 weeks the group will answer the short follow-up questionnaire over the phone. This questionnaire evaluates adherence to practice and intention to continue practicing Tai Chi after the end of the study. The figure illustrates this process.
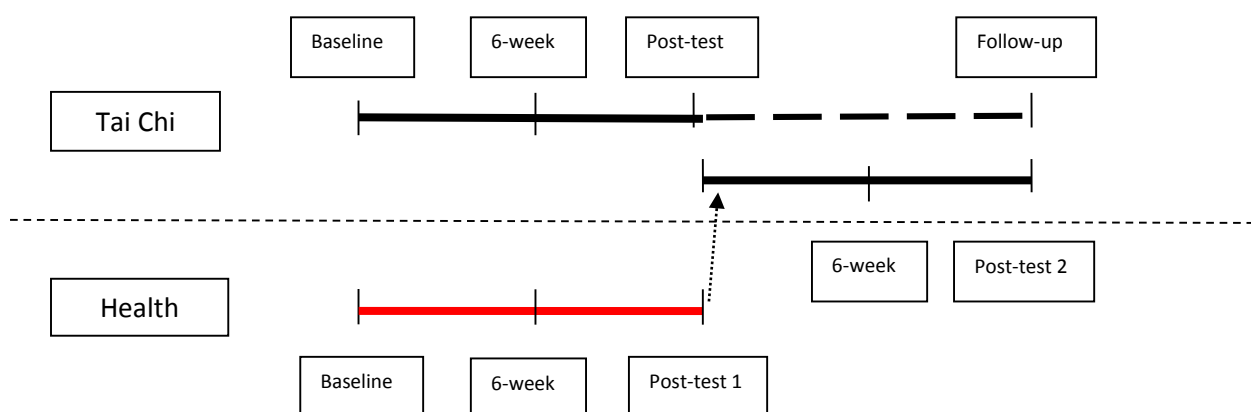
Ultimately, your participation will be for approximately 6 months, and **all** participants will receive the instruction in Tai Chi. Throughout the study you will be asked to continue to follow your regular medical care, your prescribed medications and other recommendations from your primary care provider.

What are the potential risks and discomforts?

The likely risks and discomforts expected in this study are:

Assessment of A1C does not represent more than minimal risk since this is exactly the same procedure and requires the same amount of blood necessary to measure glucose levels during daily self-monitoring practice. Minimal bruising and pain may be expected but will disappear within a day or two. All precautions for risk-free procedures will be taken. Disposal of contaminated materials will be done according to standard hygienic procedures. Even though the assessments will be done while participants are in a group, the measurement and disclosure of the actual A1C value, blood pressure and weight will be done individually and in private. You will be able to share this information with your primary care provider.

Risk of injury during the exercise classes is possible but we have been taken precautions to ensure comfortable, well ventilated, spacious rooms with even floors and minimal obstacles for the safe practice of physical activity. Mild aching after the first sessions will be expected but should not limit mobility for activities of daily living. Aching will get better within a couple of days. You will be recommended to avoid strain during the practice in class and at home. All participants will be instructed on safety tips for exercise and will receive the EASY flyer on safety tips.

Risk of hypoglycemia: Although you may be familiar with the management of your hypoglycemic episodes, you are advised to test your blood glucose levels, and eat something prior to class to avoid hypoglycemia during class. An emergency kit with glucose tablets, and refreshments and water and snacks will be available at every class to attend to the risk of hypoglycemia or dehydration. In case of an

APPENDIX C (continued)

episode, we will have you lay down with legs up, will measure your glucose levels, and give you sweet drinks. We will measure your glucose every 15 minutes until you recover. You may be referred to your provider to adjust your medication or self-care plan.

Psychosocial harm: although anxiety or embarrassment may result from responding to the questionnaires, there is minimal risk of harm. The questionnaires are commonly used in research. Your personal information will remain private and other members of the group will not have access to it. If you feel distressed, you may be referred to your health care provider. There is the risk of breach of privacy and/or confidentiality if others find out that you are participating in the research; or they may find out your personal information collected during the research. The research team will make sure the information provided remains private and is not accessed by other members of the group. Individuals will be aware of other people's participation in the study. They will be advised to maintain confidentiality about that, but we cannot guarantee that it will be observed by all.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any new findings (either good or bad), such as changes in the risks or benefits resulting from participation in this type of research or new alternatives to participation. The new information might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

Based on experience with physical activity in patients with diabetes, researchers believe it may be of benefit to subjects with your condition. However, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

It is hoped that knowledge gained from this research may benefit other Hispanic/Latino older adults with type 2 diabetes in the future.

What other options are there?

If you decide not to enter this study, there are other options available to you, such as yoga, other types of physical activity and other types or relaxation and meditation that may have similar effects. The Principal Investigator will discuss these with you. You do not have to be in this study to be treated for diabetes, or to receive exercise instruction.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

APPENDIX C (continued)

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:
- Funding Agency, such as the National Institutes of Health
- UIC Office for the Protection of Research Subjects, State of Illinois Auditors, or
- As demanded by the law.

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research.

All research personnel including exercise instructors have received certification on the ethical management of confidential information. Your information (questionnaires, etc) will be assigned a number and cannot be identified by your name. This ID # will be used for data collection, entry and analysis. Consent forms containing the ID and your name will be stored separate from other paper data forms, and under key at designated secured cabinets at IHRP- 5th floor. The key will be kept at the PI desk. These paper forms with identifiers will be destroyed at the end of the study. Paper data forms without identifiers will be entered in the computer designated to this project at IHR, and kept under key at designated metal cabinets until the completion the project. Electronic data files will be stored in the IHRP I-Drive under password protection. Only the PI, Faculty sponsor, and co-investigators will have access to the paper and electronic files.

Only information with the ID# will be used for the analysis of data and publication of results. Data without names will be kept for 5 years. These data are expected to provide the basis for subsequent research proposals. The PI will maintain these data under key in a secured cabinet until all data analyses, publications and grant proposals related to the topic are completed. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

<u>What if I am injured as a result of my participation?</u>

As mentioned above, we have taken every precaution to minimize the risk of injury related to your participation in the study. The practice of exercise in older adults is recommended to strengthen the lower and upper body and ultimately, to avoid risk of falling or other types of injury. You may have health complications related to the natural progression of diabetes. Even in this case, the practice of exercise as provided by the researchers is advisable to maintain good management of the disease and delay complications. We recommend that you observe all measures of safety: do not bend over below the waist, do not strain when performing the exercise, do not lift heavy weights, and wear appropriate clothing and shoes for exercising. However, if you think you may have medical problems or side effects from taking part in this research study, or if you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through:

- The UIC Medical Center OR
- Your regular doctor OR
- The treatment center or clinic of your choice.

If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

APPENDIX C (continued)

You may contact the researcher Amparo Castillo at 312-996-0683 to talk to them about your illness or injury.

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for the University to provide free medical care or to pay for research-related illnesses or injuries, or for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

By signing this form you will not give up any legal rights.

What are the costs for participating in this research?

There are no costs to you for participating in this research. Water and refreshments will be provided by the researchers at every Tai Chi instruction session.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will receive free instruction in one of the exercise modalities, but you will not receive payment for attending the classes. All participants will be compensated for their time when completing the baseline and post-test assessments at the end of each course, which includes responding to questionnaires, measuring A1C and blood pressure. For each one of these assessment sessions participants will receive $20 in cash or as a gift card. Participants initially assigned to the Tai Chi classes will receive a total of $40 (forty dollars). Those who are initially assigned to the health/exercise advice group will have the opportunity to participate in up to three assessment sessions, and will receive $20 per session for a possible total of $60 (sixty dollars). Participants will not receive any money for the assessments in which only the short questionnaire will be applied. These are at week 6 into the Tai Chi instruction for both groups, and at the end of the 3-month follow-up for the original Tai Chi group. Instead, their name will be entered in a raffle to win small gifts or gift cards that will take place at the end of the classes. If you withdraw from the study or the researchers determine the termination of your participation before completion, you will not receive money for the assessments that will be missed.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC. You are free to withdraw from the study at any time without any consequences.

You have the right to leave the study at any time without penalty. If you leave the study before the final planned study visit, the investigator may ask you to complete the final steps.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:
- We believe it is in your best interest;
- You were to object to any future changes that may be made in the research plan;

APPENDIX C (continued)

- If the funds for the study were suddenly terminated;
- If you experienced significant injury or worsening of health status from the practice of exercise;
- If your physician recommends it.

In the event you withdraw or are asked to leave the study, you will still be compensated for the assessments you provide as described above.

Who should I contact if I have questions?

Contact the researchers Amparo Castillo at 312-996-0683 or Dr. Laurie Ruggiero at 312-413-9825 or send an email at amparo@uic.edu:
- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the exercise), and/or
- if you have questions, concerns or complaints about the research.

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____   _____
Signature   Date

_____
Printed Name

_____   _____
Signature of Person Obtaining Consent   Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent

APPENDIX C (continued)

Universidad de Illinois en Chicago
Información y consentimiento de participación en un estudio de investigación biomédica
REDUCCION DE ESTRES CON TAI CHI PARA HISPANOS DE LA
TERCERA EDAD CON DIABETES

Se le ha pedido que participe en un estudio de investigación. Los investigadores tienen la obligación de suministrarle un formulario de consentimiento como el que tiene en sus manos para contarle en qué consiste el estudio de investigación, explicarle que toda participación es voluntaria, describir los riesgos y ventajas de participar, y ayudarle a tomar una decisión informada. No dude en consultar con los investigadores cualquier duda que pueda tener.

Nombre y cargo del investigador principal: Amparo Castillo
Departamento: Institute for Health Research and Policy
Dirección e información de contacto: 1747 West Roosevelt Road- 5th floor; Chicago, IL 60612; 312-996-0683
Este proyecto está patrocinado por el Instituto Nacional del Envejecimiento de los Institutos Nacionales de Salud, a través del Centro Roybal para la Promoción de Salud de la Universidad de Illinois en Chicago.

¿Por qué se me pide participar?

Se le ha pedido que participe en un estudio que investiga la efectividad de una modalidad de actividad física para reducir los niveles de azúcar en la sangre, la presión arterial y los niveles de estrés psico-social. Este estudio compara la práctica tradicional china del Tai Chi con recomendaciones para hacer ejercicio y para el cuidado de la salud, en personas hispano/latinas de la tercera edad con diabetes tipo 2.

Se le ha pedido que participe en este estudio de investigación porque usted se identifica como un hispano/latino(a), de 50 a 80 años de edad, tiene diagnóstico de diabetes tipo 2, no tiene complicaciones o condiciones de salud importantes que puedan interferir con la práctica del ejercicio, usted no practica ejercicio regularmente, usted no estará viajando fuera de la ciudad dentro de los próximos 6 meses, no ha recibido entrenamiento previo en técnicas de relajación, yoga o Tai Chi, y usted esta dispuesto a firmar un formulario de consentimiento.

Su participación en este estudio de investigación es voluntaria. Tanto si decide participar como si no, su relación actual o futura con la Universidad de Illinois en Chicago no se verá afectada por dicha decisión. **Si decide participar, es libre de retirarse en cualquier momento sin que ello afecte a dicha relación.**

Estimamos que unos 70 sujetos participarán en este estudio de investigación en la UIC.

¿Cuál es el objetivo de esta investigación?

El objetivo de este estudio es averiguar si Tai Chi puede reducir el A1C, el estrés y la presión arterial en Hispano/Latinos de la tercera edad con diabetes tipo 2, comparado con recomendaciones para hacer ejercicio y cuidar de la salud. La investigación ha encontrado que el estrés aumenta la presión arterial y los niveles de azúcar en la sangre; Hispano/Latinos de la tercera edad experimentan mucho estrés y no hay programas que les enseñen a reducir o manejar el estrés. Tai Chi es una forma de actividad física y

APPENDIX C (continued)

una técnica de reducción del estrés que reduce los niveles de presión arterial y azúcar en la sangre y mejora la calidad de vida de muchas personas de la tercera edad. No hay estudios de Tai Chi en hispano/latinos. Este estudio también desea averiguar qué tanta receptividad pueden tener los hispano/latinos por el Tai Chi comparado con el ejercicio de baja intensidad. Las recomendaciones para hacer ejercicio y para cuidar de la salud se le darán a los participantes a través de documentos impresos como panfletos y folletos que ofrecen información adecuada acerca del cuidado de la diabetes, incluyendo sugerencias para la dieta y el ejercicio, y que se enviarán por correo,

¿Qué procedimientos integran el estudio?

Este estudio de investigación se realizará en South Chicago, en diferentes locales. Las clases se realizarán en el solarium del segundo piso de Chicago Family Health Center y en Victory Center en South Burley Avenue.

Tendrá que acudir al centro de estudio 26 veces durante los próximos 6 meses Estas incluyen 2 visitas para evaluaciones que durarán aproximadamente 2 horas cada una; y 24 visitas para las clases de ejercicio que durarán 1 hora, dos veces por semana, por 12 semanas.

Cuatro evaluaciones se realizarán durante el curso del estudio. Dos evaluaciones completas que incluyen medir el azúcar, la presión arterial, el peso, y cuestionarios. Dos evaluaciones serán cuestionarios cortos que podrán hacerse en persona o por teléfono. Una vez que usted haya aceptado participar en el estudio y haya firmado el formulario de consentimiento, se realizará la evaluación inicial. En esta ocasión, usted dará una gota de sangre para medir su A1C, se le medirá la presión arterial, la talla y el peso, y contestará un cuestionario. Esta evaluación podrá tomar hasta dos horas de su tiempo.

Despues de esto, se le asignará al azar la participación en uno de los dos grupos. Usted no podrá elegir su grupo. La selección de su grupo se hará como echando al aire una moneda.

Uno de los grupos recibirá instrucción en Tai Chi al principio del estudio, y el otro grupo recibirá inicialmente los consejos sobre salud y ejercicio que están libres de seguir, pero recibirá la instrucción en Tai Chi después de un periodo de espera de aproximadamente 12 semanas. Las clases en ambos grupos serán dirigidas por un instructor bilingüe y certificado.Usted tomará las clases dos veces por semana por 12 semanas. Las clases durarán una hora. Cada clase tendrá hasta 18 participantes. A usted se le pedirá que practique en casa cada día por lo menos 5 minutos.

En la semana 6 del estudio, los participantes recibiendo las clases de Tai Chi contestarán un cuestionario corto (de apenas 5 minutos) acerca de su experiencia con la práctica del ejercicio de Tai Chi, las cosas que hacen fácil o difícil practicarlo, y cuántos minutos al dia ha estado practicándolo. Al final de las 12 semanas ambos grupos, los que reciben Tai Chi y los que reciben consejos en salud recibirán la evaluación final completa que incluye contestar otro cuestionario y medirle de nuevo el A1C, la presión arterial y el peso. Esta evaluación también tomará alrededor de dos horas de su tiempo.

Despues de esta evaluación, el grupo que recibe consejos sobre salud/ejercicio se cruzará a tomar el curso de Tai Chi. Las clases serán exactamente como las del primer grupo; de una hora de duración, dos veces por semana por 12 semanas. En la semana 6 de las clases, los participantes contestarán el corto cuestionario de seguimiento. Al final de las 12 semanas de instrucción este grupo recibirá otra evaluación completa que incluye contestar nuevamente un cuestionario y medirle el A1C, la presión

APPENDIX C (continued)

arterial y el peso. Esta evaluación también tomará dos horas.

Mientras tanto, el grupo que recibió Tai Chi al principio, se espera que practique en casa por otras 12 semanas. Al final de esas 12 semanas el grupo también contestará por teléfono un corto cuestionario de seguimiento. Este cuestionario hace preguntas sobre la adherencia a la práctica y la intención de continuar practicando Tai Chi después de terminar el proyecto de investigación. La figura ilustra el proceso.
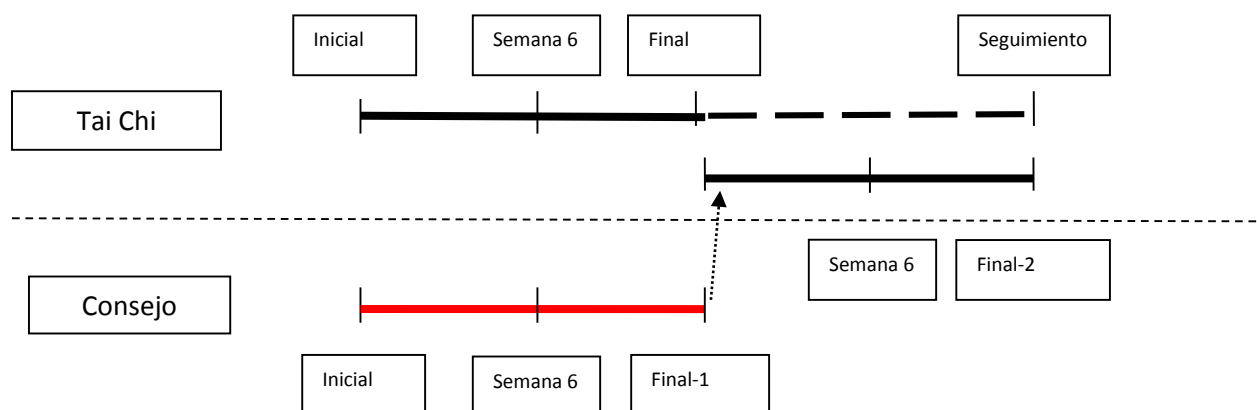
Al final, su participación será de aproximadamente 6 meses, y **todos** los participantes recibirán la instrucción en Tai Chi. A lo largo del estudio se le pedirá que siga las recomendaciones de cuidado médico, las prescripciones de medicamentos y otras recomendaciones de su proveedor de salud. NO deberá cambiar nada sin la aprobación de su proveedor de salud.

¿Cuáles son los posibles riesgos y molestias?

Los riesgos y molestias probables que podrían presentarse en este estudio son:
Medida de A1C: no representa mas que riesgo mínimo ya que es el mismo procedimiento y la misma cantidad de sangre (una gota) necesaria para medir niveles de glucosa durante la práctica diaria de auto-monitoreo. Es de esperar que haya amoratamiento y dolor en el area del pinchazo pero deberá desaparecer en uno o dos días. Se tomarán todas las precauciones necesarias para evitar riesgos en estos procedimientos. Los materiales contaminados se recogerán en un recipiente especial y se deshecharan siguiendo estándares de higiene. Aun cuando las evaluaciones se harán en grupo, las mediciones de A1C, peso y presión arterial se harán individualmente y en privado, y esta información no será revelada al grupo. Usted podrá sin embargo, compartir esta información con su proveedor de salud.

Riesgo de accidente durante las clases de ejercicio es posible, pero se han tomado precauciones para asegurar que los salones de ejercicio son cómodos, bien ventilados, espaciosos, con pisos planos y sin obstáculos para la práctica segura de actividad física. Es de esperar que haya dolor muscular pasajero después de las primeras sesiones de ejercicio, pero esto no deberá limitar la movilidad para las actividades de la vida diaria. El dolor mejorará en un par de días y se le recomendará a usted que evite esfuerzos extremos en la práctica de ejercicio durante la clase y en casa. Todos los participantes recibirán instrucciones sobre las medidas de seguridad que se deben observar para hacer ejercicio y recibirán el volante que se adjunta.

APPENDIX C (continued)

<u>Riesgo de hipoglicemia</u>: Aunque usted puede estar familiarizado con el manejo de sus episodios de hipoglicemia, se le recomienda medir sus niveles de azúcar y comer algo antes de la clase. Un kit de emrgencia con tabletas de glucosa, agua y refrescos dulces y refrigerio estarán disponibles en cada sesión para atender al riesgo de hipoglicemia o deshidratación. En caso de tener un episodio, se le tendera en el piso con las piernas elevadas y se le dara a beber jugos dulces. Le mediremos el azúcar cada 15 minutos hasta que se recupere. Se le recomendará ver a su médico para que le ajuste el plan de medicamentos.

<u>Riesgo de daño psicológico</u>: la revelación de información personal en los cuestionarios puede hacerle sentir ansiedad o vergüenza. Nos aseguraremos de que aunque los cuestionarios se contestarán en grupo, la información contenida en ellos se mantendrá en privado y no será revelada accidentalmente a otras personas del grupo. Se le podrá referir a su proveedor de salud si usted lo considera reconfortante o necesario. Existe tambien el riesgo de que se pierda la privacidad o confidencialidad si otras personas se dan cuenta de que usted está participando en la investigación, o si ellos se enteran de información privada suya durante el curso del estudio. El equipo de investigación va a asegurarse que que la información que usted revela se mantenga en privado y no sea de acceso a otros miembros del grupo. Los participantes se enterarán de quiénes más están participando en el estudio. A todos se les pedirá que mantengan la confidencialidad acerca de esto pero no podemos garantizar que todos la cumplan.

¿Se me dará a conocer toda nueva información que pueda afectar mi decisión de participar en el estudio?

Durante el transcurso del estudio, se le informará de cualquier nuevo resultado (ya sea bueno o malo), como cambios en los riesgos o beneficios derivados de la participación en la investigación o nuevas alternativas a dicha participación, que pudieran afectar a su decisión de permanecer en el estudio. Si se le da nueva información, deberá obtenerse de nuevo su consentimiento para seguir participando en este estudio.

¿Cuáles son los beneficios de participar en el estudio de investigación?

Según se infiere de la experiencia con actividad física en pacientes con diabetes tipo 2, los investigadores creen que podría ser beneficioso para personas con su condición de salud. No obstante, no puede saberse a ciencia cierta si el tratamiento será beneficioso en su caso particular ya que las personas responden de forma diferente a los tratamientos.

Confiamos en que el conocimiento adquirido de esta investigación pueda beneficiar a otras personas con diabetes tipo 2 en el futuro.

¿Qué otras opciones existen?

Si decide no inscribirse en este estudio, existen otras posibilidades médicas para usted, tales como yoga, otros tipos de actividad física y otros tipos de relajación y meditación que pueden tener efectos similares. La investigadora principal del estudio las comentará con usted. No necesita participar en este estudio para recibir tratamiento para la diabetes, o para recibir instrucción en Tai chi o en ejercicio de baja intensidad.

APPENDIX C (continued)

¿Cómo se tratará la privacidad y la confidencialidad?

Las personas con conocimiento de su participación como sujeto en la investigación son los miembros del equipo de investigación y, si es pertinente, los médicos y el personal de enfermería que lo atienden. Durante la investigación, sin su autorización por escrito no se divulgará a otras personas ninguna información acerca de usted ni suministrada por usted, salvo que sea necesario para proteger sus derechos o su bienestar (por ejemplo, si usted se lesiona y necesita atención médica urgente o cuando la Oficina para la Protección de los Seres Humanos en la Investigación de la UIC supervisa la investigación o el proceso de consentimiento) o si así lo exige la ley.

Los datos del estudio que le identifican individualmente y el formulario de consentimiento firmado por usted serán examinados o copiados para analizar la investigación por:
- El organismo de financiación, tal como los Institutos Nacionales de Salud
- La Oficina para la Protección de los Seres Humanos en la Investigación de la UIC, el Estado de Illinois, auditores, o
- A quienes lo requiera la ley.

Un posible riesgo de la investigación es que su participación en ella y la información sobre usted y relativa a su salud podrían pasar a conocimiento de personas ajenas a la investigación.
Todo el personal de investigación incluyendo los instructores, han recibido entrenamiento y certificacion en el manejo ético de información confidencial. A la información que usted provea en cuestionarios y mediciones, se le asignará un número (código) y no podrá ser identificada por su nombre. Este número sera utilizado para la colección de datos, la entrada de datos en el computador y para el análisis estadistico. Los formularios de consentimiento que contienen el código y su nombre se guardarán por separado de otros documentos, y bajo llave en gabinetes metálicos seguros y designados para esto, localizados en el 5th piso del edificio del Instituto de Investigaciones en Salud y Política (IHRP, por sus siglas en ingles). La llave de este gabinete sera guardada bajo llave en el escritorio de la investigadora principal. Los papeles que contengan información de los participantes se entrarán en archivos electrónicos en un computador designado para este proyecto en IHRP. Los papeles que contengan nombres se mantendrán bajo llave en gabinetes metálicos y serán destruidos cuando se termine el estudio. Los archivos electrónicos serán guardados en el I-Drive de IHRP protegidos con una clave y se mantendrán hasta 5 años despues de terminar el estudio. Solo la investigadora principal, la profesora de la Facultad Dra. Ruggiero y las co-investigadoras tendrán acceso a los archivos en papel y electrónicos. Solo información con números de identificación o códigos será usada para el analisis estadistico de datos, y se mantendrá por 5 años. Estos datos serán la base para próximas propuestas de investigación. La investigadora principal mantendrá esta información bajo llave hasta que todos los análisis estadísticos, las publicaciones y las propuestas de nuevos proyectos se hayan completado. En caso de que los resultados de la investigación se publiquen o comenten en congresos, no se incluirá ninguna información que pueda revelar su identidad.

¿Qué sucederá si me lesiono como consecuencia de mi participación?

Como se mencionó anteriormente, hemos tomado todas las precauciones necesarias para minimizar el riesgo de accidente relacionado con su participación en el estudio. La práctica del ejercicio en adultos de la tercera edad es recomendada para fortalecer la parte inferior y superior del cuerpo, y para evitar caídas y fracturas. Usted puede tener complicaciones relacionadas con la progresión natural de la diabetes. Aun en este caso, la práctica de ejercicio como se le proporciona en este estudio, es recomendada para

APPENDIX C (continued)

mantener un buen manejo de la enfermedad y demorar las complicaciones. Nosotros recomendamos que usted observe medidas de seguridad: no doble el cuerpo por debajo de la cintura, no exagere el esfuerzo cuando haga los ejercicios, no levante pesas, y use ropas y zapatos apropiados para hacer ejercicio. Sin embargo, si usted cree que tiene problemas médicos o efectos secundarios derivados de su participación en este estudio de investigación, o si usted cree que ha enfermado o sufrido una lesión como consecuencia de participar en este estudio, puede obtener tratamiento a través de:

- El Centro Médico de la UIC O
- Su médico habitual O
- El centro de tratamiento o clínica de su elección.

Si busca tratamiento médico, lleve una copia de este documento porque podría ser de ayuda para los médicos del centro donde busque tratamiento. Además, proporcionará a los médicos del centro donde recibe tratamiento información que podrían necesitar si quieren ponerse en contacto con los médicos de la investigación.

Puede ponerse en contacto con la investigadora Amparo Castillo en el 312-996-0683 para comentar con ella su enfermedad o lesión.

Se le facturará a usted o a su compañía de seguro por estos cuidados médicos. Su compañía de seguro podría no pagar parte o la totalidad de estos cuidados médicos debido a su participación en un estudio de investigación. No existen planes para que la universidad proporcione atención médica gratuita o pague por enfermedades o lesiones relacionadas con la investigación, o para que ofrezca otras compensaciones (tales como días de sueldo perdidos o dolor y sufrimiento) por enfermedades o lesiones relacionadas con la investigación.

Al firmar este formulario, usted no renuncia a ninguno de sus derechos legales.

¿Cuáles son los costos de participar en esta investigación?

No hay costos para usted por participar en esta investigación. Agua y refrescos le serán proporcionados gratuitamente por los investigadores durante las clases.

¿Se me reembolsarán algunos de mis gastos o se me pagará por mi participación en este estudio de investigación?

Recibirá instrucción gratuita en una de las modalidades de ejercicio, pero no se le pagará por asistir a las clases. A todos los participantes se les recompensará por su tiempo cuando deban completar las evaluaciones al principio y al final de cada curso, lo que incluye llenar los cuestionarios, y medir el A1C, el peso y la presión arterial. Por cada una de estas sesiones de evaluación los participantes recibirán $20 dólares en efectivo o en una tarjeta de regalo. Los participantes que sean inicialmente asignados a las clases de Tai Chi recibirán un total de $40 (cuarenta dólares). Aquellos que inicien el estudio en el grupo que recibe consejos de salud participarán en tres sesiones de evaluación y recibirán $20 dólares por cada sesión, para un total de $60. Participantes no recibirán dinero por el cuestionario corto de la semana 6. En su lugar, su nombre entrará en una rifa para ganar pequeños regalos o tarjetas que se rifarán all final de las clases. Si usted se retira del estudio, o si los investigadores consideran que se debe terminar su participación antes de terminar las clases, usted no recibirá dinero por las evaluaciones que dejarán de hacerse.

APPENDIX C (continued)

¿Puedo retirarme o ser eliminado del estudio?

 Si decide participar, usted es libre de retirar su consentimiento y dejar de participar en cualquier momento sin que ello afecte su atención futura en la UIC. Usted tiene el derecho de abandonar el estudio en cualquier momento sin ninguna penalización. Si abandona el estudio antes de la última visita planificada, el investigador podría pedirle que complete los últimos pasos.

Los investigadores y el patrocinador tienen también derecho a interrumpir su participación en este estudio sin su consentimiento si:
- Creen que es lo más conveniente para usted;
- Usted fuera a oponerse a cambios futuros que puedan hacerse en el plan del estudio;
- Si el patrocinador de la investigación suspende los fondos para el proyecto,
- Si sufre un accidente o se empeora su estado de salud por la práctica del ejercicio; y
- Si su médico lo recomienda.

En el caso de que usted se retire o de que se le pida que abandone el estudio, se le recompensará por las evaluaciones realizadas hasta esa fecha, como se ha descrito anteriormente.

¿A quién debo contactar si tengo preguntas?

Póngase en contacto con los investigadores Amparo Castillo llamando al 312-996-0683, o Laurie Ruggiero al 312-413-9825, o por correo electrónico a amparo@uic.edu:
- si tiene preguntas acerca de este estudio o de su participación en él,
- si cree que ha sufrido una lesión relacionada con la investigación (o una mala reacción al ejercicio), o
- si tiene preguntas, preocupaciones o quejas sobre la investigación.

¿Cuáles son mis derechos como sujeto de investigación?

Si tiene preguntas sobre sus derechos como sujeto de investigación o preocupaciones o quejas, o quiere darnos su opinión, puede llamar a la Oficina para la Protección de los Seres Humanos en la Investigación (OPRS, Office for the Protection of Research Subjects) al 312-996-1711 o 1-866-789-6215 (llamada gratuita) o enviar un mensaje por correo electrónico a la OPRS a uicirb@uic.edu.

Recuerde:
Su participación en esta investigación es voluntaria. Su decisión sobre su participación no afectará a su relación actual o futura con la universidad. Si decide participar, es libre de retirarse en cualquier momento sin que ello afecte dicha relación.

Firma del sujeto o del representante legalmente autorizado

He leído (o alguien me ha leído) la información anterior. He tenido oportunidad de hacer preguntas, y éstas se han contestado a mi entera satisfacción. Acepto participar en esta investigación. Se me entregará una copia de este formulario firmado y fechado.

APPENDIX C (continued)

_____   _____
Firma   Fecha

_____
Nombre en letra de imprenta

_____   _____
Firma de la persona que obtiene el consentimiento   Fecha (debe ser la misma que la del
sujeto)

_____
Nombre de la persona que obtiene el consentimiento en letra de imprenta

APPENDIX D

<table>
<tr><td>Screening #:

ID #:</td><td>University of Illinois at Chicago
Stress Reduction for
Elderly Hispanics Study
(StREHS)
-Phase 2-</td></tr>
</table>

Intake Questionnaire

We would like to ask you some questions about your background, your health, self-care activities, and levels of stress. Your answers are confidential. Let us know if you have any questions before we begin.

Staff Member: _____

Date of Completion: _____

A. Demographics: First, we want to ask you some basic questions about yourself and your living situation.	
Age (years):	**Sex:** [ ] 1. Female [ ] 2. Male
Country of Birth: [ ] 1. U.S. [ ] 2. Mexico [ ] 3. Other:	
Number of years lived in U.S. _____	**Education (years):**
Primary Language: [ ] 1. English [ ] 2. Spanish [ ] 3. Other:	
Marital Status: [ ] 1. Married/Living together [ ] 2. Divorced /Separated [ ] 3. Widowed [ ] 4. Never Married	

Annual Household Income: [ ]1. <15k
                [ ]2. 15k-24,999
                [ ]3. 25k-34,999
                [ ]4. 35k-44,999
                [ ]5. 45k- 54,999
                [ ]6. ≥ 55K
                [ ]7. Don't know/Not sure	

Employment: [ ]1. Employed for wages
                [ ]2. Self-employed
                [ ]3. Out of work for MORE than 1 year
                [ ]4. Out of work for LESS than 1 year
                [ ]5. A homemaker
                [ ]6. Retired
                [ ]7. Unable to work	

Education: [ ]1. Never attended school or only attended kindergarten
                [ ]2. Grades 1-8 (Elementary)
                [ ]3. Grades 9-11 (Some high school)
                [ ]4. Grades 12 or GED (High school graduate)
                [ ]5. College 1-3 years (some college or technical school)
                [ ]6. College 4 years or more (College Graduate)	

Do you have any kind of health care coverage, including health insurance, prepaid plans (i.e., HMO's) or government plans (i.e., Medicare)? [ ]1. Yes [ ]2. No [ ]3. Don't Know/Not Sure	
How many people in your household have diabetes? [ ]1. Number of People_____ [ ]2. None	
How long have you had diabetes?	**Year of diagnosis:**

APPENDIX D (continued)

B. Diabetes Self-care: The questions that follow ask about your self-care activities during the past 7 days. If you were sick during those 7 days, think back to the last 7 days that you were not sick. Please circle your answer.								
Diet:								
1. How many of the last SEVEN DAYS have you followed a healthful eating plan?	0	1	2	3	4	5	6	7
2. On average, over the past month, how many DAYS PER WEEK, have you followed your eating plan?	0	1	2	3	4	5	6	7
3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
4. On how many of the last SEVEN DAYS did you eat high fat foods (i.e., red meat, full fat dairy products, etc.)?	0	1	2	3	4	5	6	7
Exercise:								
5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (i.e., swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
Blood Sugar Testing:								
7. On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your heath care provider?	0	1	2	3	4	5	6	7
Medication:								
9. Are you currently using: ☐ Pills ☐ Insulin ☐ Other injected meds ☐ Both ☐ None								

C. Diabetes Distress Scale: Living with diabetes can sometimes be tough. There may be numerous problems and hassles concerning diabetes and they can greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas which people with diabetes may experience. Consider the degree to which each of the times may have distressed or bothered you during the past month and circle the appropriate number.	Not a problem		Moderate problem			Serious problem	
1. Feeling that diabetes is taking up too much of my mental and physical energy every day	0	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care	0	1	2	3	4	5	6
3. Feeling angry, scared and/or depressed when I think about living with diabetes	0	1	2	3	4	5	6
4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes	0	1	2	3	4	5	6
5. Feeling that I am not testing my blood sugars frequently enough	0	1	2	3	4	5	6
6. Feeling that I am often failing with my diabetes regimen	0	1	2	3	4	5	6
7. Feeling that friends or family are not supportive enough of my self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods)	0	1	2	3	4	5	6
8. Feeling that diabetes controls my life	0	1	2	3	4	5	6
9. Feeling that my doctor doesn't take my concerns seriously enough	0	1	2	3	4	5	6
10. Not feeling confident in my day-to-day ability to manage diabetes	0	1	2	3	4	5	6
11. Feeling that I will end up with serious long-term complications, no matter what I do	0	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan	0	1	2	3	4	5	6

APPENDIX D (continued)

13. Feeling that friends or family don't appreciate how difficult living with diabetes can be	0	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	0	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly about my diabetes	0	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self-management	0	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like	0	1	2	3	4	5	6

D. Perceived Stress Scale: These questions ask about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way:	Ratings: 0= Never 1= Almost never 2= Sometimes 3= Fairly often 4= Very often				
1. In the last month, how often have you been upset for something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

E. Hispanic Stress Inventory-Immigrants: Please, rate the level of stressfulness of each of these incidents:	Ratings: 1=Not at all stressful 2= 3= 4= 5= Extremely stressful				
1. Because I do not know enough English, it has been difficult for me to interact with others	1	2	3	4	5
2. Because I am Latino I have been expected to work harder	1	2	3	4	5
3. I have felt pressured to learn English	1	2	3	4	5
4. Because I am Latino I have had difficulty finding the type of work I want.	1	2	3	4	5
5. I have been forced to accept low paying jobs.	1	2	3	4	5
6. I have had to watch the quality of my work so others do not think I am lazy.	1	2	3	4	5
7. Because of my poor English people have treated me badly.	1	2	3	4	5
8. Because I am Latino it has been hard to get promotion or salary raises.	1	2	3	4	5
9. My income has not been sufficient to support my family or myself.	1	2	3	4	5
10. There have been conflicts among members of my family.	1	2	3	4	5
11. There has been physical violence among members of my family.	1	2	3	4	5
12. I had serious arguments with family members.	1	2	3	4	5
13. I have felt that my children's ideas about sexuality are too liberal.	1	2	3	4	5
14. My children have talked about leaving home	1	2	3	4	5
15. My children have received bad school reports (or bad grades)	1	2	3	4	5
16. My spouse and I have disagreed on how to bring up our children.	1	2	3	4	5
17. My children have not respected my authority the way they should.	1	2	3	4	5

APPENDIX D (continued)

F. Physical Activity Questionnaire	Ratings: 1 = Much More Active 2 = Somewhat More Active 3 = About the Same 4 = Somewhat Less Active 5 = Much Less Active 6 = Not Applicable					
1. Thinking about the things you do at work, how would you rate yourself as to the amount of physical activity you get compared with others of your age and sex?	1	2	3	4	5	6
2. Now thinking about the things you do outside of work, how would you rate yourself as the amount of physical activity you get compared with others your age and sex?	1	2	3	4	5	6
3. Do you regularly engage in strenuous activity or hard physical labor?	1	2	3	4	5	6
4. Do you exercise or labor at least three times a week?	1	2	3	4	5	6

G. Physical activity self-efficacy scale: How sure are you that you could overcome the following barriers in performing your exercises?	Ratings: 1 = Very unsure 2 = Rather unsure 3 = Rather sure 4 = Very sure			
I can manage to perform my exercises……	1	2	3	4
1. …even when I have worries and problems	1	2	3	4
2. … even if I fell depressed	1	2	3	4
3. …even when I feel tense	1	2	3	4
4. …even when I am tired	1	2	3	4
5. …even when I am busy.	1	2	3	4

H. Functional Social Support Questionnaire: Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and circle the number that is closest to your situation.	Ratings: 1 = As much as I would like 2 = 3 = 4 = 5 = 6 = Much less than I would like					
I get……….						
1. People who care what happens to me………………	1	2	3	4	5	6
2. Love and affection………………………..	1	2	3	4	5	6
3. Chances to talk to someone about problems at work or with my housework ………………………………..	1	2	3	4	5	6
4. Chances to talk to someone I trust about my personal and family problems……………………………..	1	2	3	4	5	6
1. Chances to talk about money matters………………………	1	2	3	4	5	6
6. Invitations to go out and do things with other people…………..	1	2	3	4	5	6
7. Useful advice about important things in life……………	1	2	3	4	5	6
8. Help when I'm sick in bed…………………….	1	2	3	4	5	6

APPENDIX D (continued)

I. Healthy Days Core Module	Rating: 1= Excellent 2= Very good 3= Good 4= Fair 5= Poor				
1. Would you say that in general your health is…	1	2	3	4	5
2. Now, thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good? Number of days: _____ [ ] None [ ] Don't know/Not sure					
3. Now, thinking about your mental health, which includes stress, depression and problems with emotions, for how many days during the past 30 days was your physical health not good? Number of days: _____ [ ] None [ ] Don't know/Not sure					
4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities such as self-care, work or recreation? Number of days: _____ [ ] None [ ] Don't know/Not sure					

J. Morisky Medication Scale: Individuals have identified several issues regarding their medication taking-behavior and we are interested in your experiences. There is no right or wrong answer. Please, answer each question based on your personal experience with your diabetes medication. Please, circle the correct number.	No	Yes
1. Do you sometimes forget to take your diabetes medication?	0	1
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your diabetes medicine?	0	1
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	0	1
4. When you travel or leave home, do you sometimes forget to bring along your diabetes medication?	0	1
5. Did you take your diabetes medication yesterday?	0	1
6. When you feel like your diabetes is under control, do you sometimes stop taking your medicine?	0	1
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?	0	1
8. How often do you have difficulty remembering to take all your medications? Please, circle the correct number.		
Never/Rarely		0
Once in a while		1
Sometimes		2
Usually		3
All the time		4

K. Biomedical Outcomes:	
Height: Weight:	BMI:
A1C: %	
Blood pressure (1): / mmHg	Average blood pressure:
Blood pressure (2): / mmHg	
Blood pressure (3): / mmHg	_____ / _____ mm Hg

APPENDIX D (continued)

Screening #:   ID #:

University of Illinois at Chicago
**Stress Reduction for
Elderly Hispanics Study
(StREHS)**

Cuestionario Inicial

Nos gustaría hacerle algunas preguntas sobre sus antecedentes, su estado de salud, actividades de auto- cuidado, y sus niveles de estrés. Sus respuestas son confidenciales. Háganos saber si tiene alguna pregunta antes de comenzar.

Supervisado por: _____

Fecha: _____

Información Demográfica:

A. Primero, queremos hacerle algunas preguntas básicas acerca de usted y su situación de vivienda.
Edad (años): ⎮ **Sexo:** [ ] 1. Femenino   [ ] 2. Masculino
País de nacimiento: [ ] 1. EE.UU.   [ ] 2. México   [ ] 3. Otro:
Número de años vividos en EE.UU. _____ ⎮ **Educación (años):**
Idioma Principal: [ ] 1. Inglés   [ ] 2. Español   [ ] 3. Otro:
Estado Civil: [ ] 1. Casado/Unión libre   [ ] 2. Divorciado/Separado   [ ] 3. Viudo   [ ] 4. Nunca se ha casado
Ingreso Anual: [ ]1. < 15k   [ ]2. 15k-24,999   [ ]3. 25k-34,999   [ ]4. 35k-44,999   [ ]5. 45k-54,999   [ ]6. >55k   [ ]7. No sé/no estoy seguro

Empleo:[ ]1. Empleado asalariado
       [ ]2. Empleado independiente
       [ ]3. Sin trabajo por **más** de un año
       [ ]4. Sin trabajo por **menos** de un año
       [ ]5. Ama de casa
       [ ]6. Retirado
       [ ]7. No puede trabajar

Educación: [ ]1. Nunca asistió a la escuela o solo asistió a kindergarten
       [ ]2. Grados del 1 al 8 (Elemental)
       [ ]3. Grados del 9 al 11 (Algo de Secundaria)
       [ ]4. Grados del 12 o GED (Graduado de Secundaria)
       [ ]5. Universidad 1 a 2 años (Algo de universidad o escuela técnica)
       [ ]6. Universidad 4 años o más (Graduado de universidad)

Tiene usted algún tipo de cobertura de cuidado de salud incluyendo seguro de salud, planes pre-pagados tales como HMO, o planes gubernamentales (por ejemplo, Medicare)?   [ ]1. Sí   [ ]2. No   [ ]3. No sé/No estoy seguro(a)
Cuántas personas en su hogar tienen diabetes?   [ ]1. Número de personas:_____   [ ]2. Ninguno
Cuánto tiempo hace que tiene diabetes?
Año en que fué diagnosticado:

B. Las preguntas siguientes son acerca de sus actividades de auto- cuidado durante los últimos 7 días. Si usted estuvo enfermo durante esos 7 días, piense en los últimos 7 días en los cuales usted no estuvo enfermo. Por favor, marque su respuesta con un círculo.								
Nutrición:								
1. ¿Cuántos de los últimos **siete días** ha seguido usted un plan de comida saludable?	0	1	2	3	4	5	6	7
2. En promedio, durante el último mes, ¿cuántos **días a la semana** ha seguido su plan de comida?	0	1	2	3	4	5	6	7

3.	¿Cuántos de los últimos **siete días** ha seguido usted un plan de comida saludable?	0	1	2	3	4	5	6	7
4.	En promedio, durante el último mes, ¿cuántos **días a la semana** ha seguido su plan de comida?	0	1	2	3	4	5	6	7
5.	¿Cuántos de los últimos **siete días** comió usted cinco o más porciones de fruta y vegetales?	0	1	2	3	4	5	6	7
6.	¿Cuántos de los últimos **siete días** comió usted comidas altas en grasa (por ejemplo, carne roja o productos lácteos sin desnatar)?	0	1	2	3	4	5	6	7
Actividad Física:									
7.	¿En cuántos de los últimos **siete días** participó usted en por lo menos 30 minutos de actividad física? (minutos totales de actividad continua, incluyendo caminar)	0	1	2	3	4	5	6	7
8.	¿En cuántos de los últimos **siete días** tomó usted parte en una sesión específica de ejercicio (como nadando, caminando, montando bicicleta) distinto al que hace en su casa o como parte del trabajo?	0	1	2	3	4	5	6	7
Monitoreo de Glucosa:									
9.	¿En cuántos de los últimos **siete días** se analizó su nivel de glucosa (azúcar en la sangre)?	0	1	2	3	4	5	6	7
10.	¿En cuántos de los últimos **siete días** se analizó su nivel de glucosa (azúcar en la sangre) el número de veces recomendado por su médico?	0	1	2	3	4	5	6	7
Medicamentos:									
9. Usted está usando: ☐ Pastillas ☐ Insulina ☐ Otro medicamento inyectable ☐ Ambos ☐ Ningún medicamento									

C. Escala de aflicción de la diabetes: Vivir con la diabetes a veces es difícil. Puede haber muchos problemas relacionados con la diabetes que puedan variar en severidad. Estos problemas varían desde molestias menores hasta dificultades muy graves. Enumeradas abajo hay 17 posibles problemas que las personas con diabetes puedan enfrentar. Considere qué tan problemáticas han sido para usted las siguientes situaciones durante el último mes, y por favor, marque con un círculo el número apropiado.	No es Problema		Problema Modera-do		Problema Grave		
18. Sentir que la diabetes está tomando mucha de mi energía mental y física todos los días.	0	1	2	3	4	5	6
19. Sentir que mi doctor no sabe lo suficiente acerca de la diabetes y el cuidado de la diabetes.	0	1	2	3	4	5	6
20. Sentirme que estoy enojada/o, con miedo y/o deprimida/o cuando pienso en vivir con diabetes.	0	1	2	3	4	5	6
21. Sentir que mi doctor no me da las recomendaciones suficientemente claras sobre cómo manejar mi diabetes.	0	1	2	3	4	5	6
22. Sentir que no me estoy analizando el nivel de azúcar en la sangre con suficiente frecuencia.	0	1	2	3	4	5	6
23. Sentir que no estoy logrando mantener mi régimen de cuidado de la diabetes.	0	1	2	3	4	5	6
24. Sentir que mis amigos o familiares no me dan suficiente apoyo en mis esfuerzos para cuidar mi diabetes (por ejemplo, planean actividades que chocan con mi horario, me animan a comer comidas inadecuadas para mí)	0	1	2	3	4	5	6
25. Sentir que la diabetes controla mi vida.	0	1	2	3	4	5	6
26. Sentir que mi doctor no toma en serio mis preocupaciones.	0	1	2	3	4	5	6
27. No sentirme segura/o de mi habilidad de manejar mi diabetes en la vida diaria.	0	1	2	3	4	5	6
28. Sentir que tendré complicaciones serias a largo plazo, sin importar lo que yo haga.	0	1	2	3	4	5	6
29. Sentir que no estoy siguiendo de cerca un buen régimen alimenticio.	0	1	2	3	4	5	6

APPENDIX D (continued)

	0	1	2	3	4	5	6
30. Sentir que mis amigos o familiares no aprecian lo difícil que es vivir con la diabetes.	0	1	2	3	4	5	6
31. Sentirme sobrecargada/o por las necesidades que requiere vivir con la diabetes.	0	1	2	3	4	5	6
32. Sentir que no tengo un doctor que pueda visitar con frecuencia para tratar mi diabetes.	0	1	2	3	4	5	6
33. Sentir que no tengo la motivación suficiente para mantener el cuidado de mi diabetes.	0	1	2	3	4	5	6
34. Sentir que mis amigos o familiares no me dan el apoyo emocional que me gustaría tener.	0	1	2	3	4	5	6

D. Escala de la Percepción del Estrés: Las siguientes son preguntas acerca de lo que usted ha sentido y pensado durante el último mes. En cada caso, por favor indique con qué frecuencia usted se siente o piensa de cierta manera:	0= Nunca 1= Casi nunca 2= Algunas veces 3= Con alguna frecuencia 4= Muy a menudo				
1. En este último mes, ¿con qué frecuencia se ha molestado usted por algo que ocurrió inesperadamente?	0	1	2	3	4
2. En este último mes, ¿con qué frecuencia se ha sentido usted incapaz de controlar las cosas importantes en su vida?	0	1	2	3	4
3. En este último mes, ¿con qué frecuencia se ha sentido usted nervioso y "estresado/a"?	0	1	2	3	4
4. En este último mes, ¿con qué frecuencia se ha sentido usted con confianza en su habilidad para manejar sus problemas personales?	0	1	2	3	4
5. En este último mes, ¿con qué frecuencia ha sentido usted que las cosas le están saliendo como usted quiere?	0	1	2	3	4
6. En este último mes, ¿con qué frecuencia ha encontrado que usted no puede con todo lo que ha tenido que hacer?	0	1	2	3	4
7. En este último mes, ¿con qué frecuencia ha sido capaz de controlar irritaciones en su vida?	0	1	2	3	4
8. En este último mes, ¿con qué frecuencia ha sentido que usted está al día con todas las cosas?	0	1	2	3	4
9. En este último mes, ¿con qué frecuencia se ha enfurecido por cosas que estaban fuera de su control?	0	1	2	3	4
10. En este último mes, ¿con qué frecuencia ha sentido que las dificultades estaban aumentando tanto que usted no podría superarlas?	0	1	2	3	4

E. Inventario Hispano del Estrés para Inmigrantes: Por favor, indique qué tan estresante es para usted cada una de las siguientes situaciones:	1=Para nada estresante 2= Un poco 3= Algo estresante 4= Estresante 5= Extremadamente estresante				
1. Porque no sé suficiente inglés, ha sido difícil para mí interactuar con otras personas	1	2	3	4	5
2. Porque soy Latino/a se espera que yo trabaje más duro	1	2	3	4	5
3. Me he sentido presionado/a para aprender inglés	1	2	3	4	5
4. Porque soy Latino/a he tenido dificultad en encontrar el tipo de trabajo que yo quiero	1	2	3	4	5
5. He sido forzado/a a aceptar trabajos de bajo salario	1	2	3	4	5
6. He tenido que vigilar la calidad de mi trabajo para que otros no piensen que soy perezoso/a.	1	2	3	4	5
7. Porque no hablo bien el inglés, la gente me ha tratado mal.	1	2	3	4	5

APPENDIX D (continued)

8. Porque soy Latino/a ha sido difícil obtener promociones o aumentos de salario.	1	2	3	4	5
9. Mi ingreso no ha sido suficiente para sostener a mi familia o sostenerme a mí mismo.	1	2	3	4	5
10. Ha habido conflictos entre miembros de mi familia.	1	2	3	4	5
11. Ha habido violencia física entre miembros de mi familia.	1	2	3	4	5
12. He tenido peleas serias con miembros de mi familia.	1	2	3	4	5
13. He sentido que las ideas de mis hijos acerca de la sexualidad son muy liberales.	1	2	3	4	5
14. Mis hijos han hablado de irse de la casa.	1	2	3	4	5
15. Mis hijos han recibido malos reportes escolares (o bajas calificaciones).	1	2	3	4	5
16. Mi esposo/a y yo hemos estado en desacuerdo sobre como criar a nuestros hijos.	1	2	3	4	5
17. Mis hijos no han respetado mi autoridad de la forma que deberían.	1	2	3	4	5

F. Cuestionario de Actividad Física	1 = Mucho más activo 2 = Un poco más activo 3 = Más o menos lo mismo 4 = Un poco menos activo 5 = Mucho menos activo 6 = No aplica					
2. Cuando piensa en las cosas que hace en su trabajo, ¿cómo se calificaría en la cantidad de actividad física que usted hace comparada con otros de su misma edad y sexo?	1	2	3	4	5	6
2. Ahora, cuando piensa en las cosas que usted hace por fuera de su trabajo, ¿cómo se calificaría en la cantidad de actividad física que usted hace comparada con otros de su misma edad y sexo?	1	2	3	4	5	6
3. ¿Hace usted regularmente actividad extenuante o trabajo físico duro?	1	2	3	4	5	6
5. ¿Hace usted ejercicio o trabajo físico laboral por lo menos tres veces a la semana?	1	2	3	4	5	6

G. Escala de Auto-eficacia en Actividad Física: ¿Qué tan seguro está usted de que podría superar las siguientes barreras para hacer ejercicio?	1 = Muy inseguro 2 = Mas bien inseguro 3 = Mas bien seguro 4 = Muy seguro			
Yo puedo arreglármelas para hacer mis ejercicios……	1	2	3	4
1. …aun cuando tengo preocupaciones y problemas	1	2	3	4
2. … aun cuando caigo deprimido/a	1	2	3	4
3. …aun cuando me siento tenso/a	1	2	3	4
4. …aun cuando estoy cansado/a	1	2	3	4
5. …aun cuando estoy ocupado/a.	1	2	3	4

H. Cuestionario de Apoyo Social Funcional: Esta es una lista de algunas cosas que otras personas nos dan o hacen por nosotros, y que pueden ser de ayuda. Por favor, lea cada frase con cuidado y marque con un círculo el número que más se acerca a su situación.	1 = Tanto como me gustaría 2 = 3 = 4 = 5 = 6 = Mucho menos de lo que me gustaría					
Yo tengo………..						
1. Personas que se preocupan por lo que me pasa a mí………………	1	2	3	4	5	6
2. Amor y afecto………………………..	1	2	3	4	5	6
5. Oportunidad de hablar con alguien acerca de mis problemas en el trabajo o con mis quehaceres de casa ………………………….	1	2	3	4	5	6

APPENDIX D (continued)

6. Oportunidad de hablar con alguien en quien confío acerca de mis problemas personales y familiares ………………………………..	1	2	3	4	5	6
7. Oportunidad de hablar acerca de asuntos de dinero …………….	1	2	3	4	5	6
6. Invitaciones para salir y hacer cosas con otras personas…………..	1	2	3	4	5	6
7. Consejos útiles acerca de cosas importantes en mi vida ………..…	1	2	3	4	5	6
8. Ayuda cuando estoy enfermo en cama …………………….	1	2	3	4	5	6

I. Módulo Central de los Días Saludables	1= Excelente 2= Muy buena 3= Buena 4= Más o menos 5= Pobre				
5. Usted diría que en general su salud es …	1	2	3	4	5

6. Ahora, pensando en su salud física, la cual incluye enfermedades y traumas físicos, ¿por cuántos días durante los pasados 30 días, su salud física no fue buena?

Número de días: _____   [ ] Ninguno   [ ] No sé/no estoy seguro/a

7. Ahora, pensando en su salud mental, la cual incluye estrés, depresión y problemas emocionales, ¿por cuántos días durante los pasados 30 días, su salud mental no fue buena?

Número de días: _____   [ ] Ninguno   [ ] No sé/no estoy seguro/a

8. Durante los pasados 30 días, ¿por cuántos días una pobre salud física o mental le impidió hacer sus actividades habituales tales como auto-cuidado, trabajo o recreación?

Número de días: _____   [ ] Ninguno   [ ] No sé/no estoy seguro/a

J. Escala de Medicamentos de Morisky: **Algunas personas han identificado problemas relacionados con el comportamiento al tomar medicamentos, y estamos interesados en su experiencia. No hay respuestas correctas o erradas. Por favor, responda cada pregunta con base en su experiencia personal con los medicamentos para su diabetes. Marque el número correcto.**	**No**	**Sí**
1. ¿Olvida usted algunas veces tomar sus medicamentos para la diabetes?	0	1
2. Las personas algunas veces no toman sus medicinas por razones distintas al olvido. Pensando en las últimas dos semanas, ¿hubo algunos días en los que usted no tomó sus medicinas para la diabetes?	0	1
3. ¿Alguna vez ha reducido o ha dejado de tomar su medicina sin decirle a su doctor porque usted se sentía peor cuando la tomaba?	0	1
4. Cuando usted viaja o sale de casa, ¿se olvida a veces de llevar sus medicinas para la diabetes?	0	1
5. ¿Tomó sus medicinas para la diabetes ayer?	0	1
6. Cuando usted siente que su diabetes está bajo control, ¿a veces deja de tomar su medicina?	0	1
7. Tomar medicinas todos los días es realmente inconveniente para algunas personas. ¿Se siente usted presionado/a a seguir su plan de tratamiento de su diabetes?	0	1
8. ¿Con qué frecuencia tiene usted dificultad para recordar tomar todas sus medicinas? Por favor, indique la respuesta correcta.		
Nunca/Raramente	0	
De vez en cuando	1	
Algunas veces	2	
Usualmente	3	
Todo el tiempo	4	

APPENDIX D (continued)

K. Resultados Bio-médicos:			
Estatura:	**Peso:**		**IMC:**
A1C: %			
Presión arterial (1):	/	**mmHg**	**Promedio de presión arterial:**
Presión arterial (2):	/	**mmHg**	
Presión arterial (3):	/	**mmHg**	**_____ / _____ mm Hg**

APPENDIX E

Screening #: ID #:

University of Illinois at Chicago
Stress Reduction for
Elderly Hispanics Study
(StREHS)
-Phase 2-

Post-test Questionnaire

We would like to ask you some questions about your health, self-care activities, levels of stress, and your experience during the exercise classes. Your answers are confidential. Let us know if you have any questions before we begin.

Staff Member: _____

Date of Completion: _____

A. Diabetes Self-care: The questions that follow ask about your self-care activities during the past 7 days. If you were sick during those 7 days, think back to the last 7 days that you were not sick. Please circle your answer.								
Diet:								
1. How many of the last SEVEN DAYS have you followed a healthful eating plan?	0	1	2	3	4	5	6	7
2. On average, over the past month, how many DAYS PER WEEK, have you followed your eating plan?	0	1	2	3	4	5	6	7
3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
4. On how many of the last SEVEN DAYS did you eat high fat foods (i.e., red meat, full fat dairy products, etc.)?	0	1	2	3	4	5	6	7
Exercise:								
5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (i.e., swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
Blood Sugar Testing:								
7. On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your heath care provider?	0	1	2	3	4	5	6	7
Medications:								
9. Did your medications change in the last **three months**? ☐ Yes ☐ No								
10. If yes, how? ☐ Increased ☐ Decreased								

APPENDIX E (continued)

B. Diabetes Distress Scale: Living with diabetes can sometimes be tough. There may be numerous problems and hassles concerning diabetes and they can greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas which people with diabetes may experience. Consider the degree to which each of the times may have distressed or bothered you during the past month and circle the appropriate number.	Not a problem		Moder ate proble m		Serious proble m		
35. Feeling that diabetes is taking up too much of my mental and physical energy every day	0	1	2	3	4	5	6
36. Feeling that my doctor doesn't know enough about diabetes and diabetes care	0	1	2	3	4	5	6
37. Feeling angry, scared and/or depressed when I think about living with diabetes	0	1	2	3	4	5	6
38. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes	0	1	2	3	4	5	6
39. Feeling that I am not testing my blood sugars frequently enough	0	1	2	3	4	5	6
40. Feeling that I am often failing with my diabetes regimen	0	1	2	3	4	5	6
41. Feeling that friends or family are not supportive enough of my self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods)	0	1	2	3	4	5	6
42. Feeling that diabetes controls my life	0	1	2	3	4	5	6
43. Feeling that my doctor doesn't take my concerns seriously enough	0	1	2	3	4	5	6
44. Not feeling confident in my day-to-day ability to manage diabetes	0	1	2	3	4	5	6
45. Feeling that I will end up with serious long-term complications, no matter what I do	0	1	2	3	4	5	6
46. Feeling that I am not sticking closely enough to a good meal plan	0	1	2	3	4	5	6
47. Feeling that friends or family don't appreciate how difficult living with diabetes can be	0	1	2	3	4	5	6
48. Feeling overwhelmed by the demands of living with diabetes.	0	1	2	3	4	5	6
49. Feeling that I don't have a doctor who I can see regularly about my diabetes	0	1	2	3	4	5	6
50. Not feeling motivated to keep up my diabetes self-management	0	1	2	3	4	5	6
51. Feeling that friends or family don't give me the emotional support that I would like	0	1	2	3	4	5	6

C. Perceived Stress Scale: These questions ask about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way:	Ratings: 0= Never 1= Almost never 2= Sometimes 3= Fairly often 4= Very often				
1. In the last month, how often have you been upset for something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

APPENDIX E (continued)

D. Hispanic Stress Inventory-Immigrants: Please, rate the level of stressfulness of each of these incidents:	Ratings: 1=Not at all stressful 2= 3= 4= 5= Extremely stressful				
1. Because I do not know enough English, it has been difficult for me to interact with others	1	2	3	4	5
2. Because I am Latino I have been expected to work harder	1	2	3	4	5
3. I have felt pressured to learn English	1	2	3	4	5
4. Because I am Latino I have had difficulty finding the type of work I want.	1	2	3	4	5
5. I have been forced to accept low paying jobs.	1	2	3	4	5
6. I have had to watch the quality of my work so others do not think I am lazy.	1	2	3	4	5
7. Because of my poor English people have treated me badly.	1	2	3	4	5
8. Because I am Latino it has been hard to get promotion or salary raises.	1	2	3	4	5
9. My income has not been sufficient to support my family or myself.	1	2	3	4	5
10. There have been conflicts among members of my family.	1	2	3	4	5
11. There has been physical violence among members of my family.	1	2	3	4	5
12. I had serious arguments with family members.	1	2	3	4	5
13. I have felt that my children's ideas about sexuality are too liberal.	1	2	3	4	5
14. My children have talked about leaving home	1	2	3	4	5
15. My children have received bad school reports (or bad grades)	1	2	3	4	5
16. My spouse and I have disagreed on how to bring up our children.	1	2	3	4	5
17. My children have not respected my authority the way they should.	1	2	3	4	5

E. Physical Activity Questionnaire	Ratings: 1 = Much More Active 2 = Somewhat More Active 3 = About the Same 4 = Somewhat Less Active 5 = Much Less Active 6 = Not Applicable					
3. Thinking about the things you do at work, how would you rate yourself as to the amount of physical activity you get compared with others of your age and sex?	1	2	3	4	5	6
2. Now thinking about the things you do outside of work, how would you rate yourself as the amount of physical activity you get compared with others your age and sex?	1	2	3	4	5	6
3. Do you regularly engage in strenuous activity or hard physical labor?	1	2	3	4	5	6
6. Do you exercise or labor at least three times a week?	1	2	3	4	5	6

F. Physical activity self-efficacy scale: How sure are you that you could overcome the following barriers in performing your exercises?	Ratings: 1 = Very unsure 2 = Rather unsure 3 = Rather sure 4 = Very sure			
I can manage to perform my exercises……	1	2	3	4
1. …even when I have worries and problems	1	2	3	4
2. … even if I fell depressed	1	2	3	4
3. …even when I feel tense	1	2	3	4
4. …even when I am tired	1	2	3	4
5. …even when I am busy.	1	2	3	4

APPENDIX E (continued)

G. **Functional Social Support Questionnaire:** **Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and circle the number that is closest to your situation.**	**Ratings:** 1 = As much as I would like 2 = 3 = 4 = 5 = 6 = Much less than I would like					
I get……….						
1. People who care what happens to me………………	1	2	3	4	5	6
2. Love and affection………………………..	1	2	3	4	5	6
8. Chances to talk to someone about problems at work or with my housework ……………………………….	1	2	3	4	5	6
9. Chances to talk to someone I trust about my personal and family problems……………………………..	1	2	3	4	5	6
2. Chances to talk about money matters…………………….	1	2	3	4	5	6
6. Invitations to go out and do things with other people…………..	1	2	3	4	5	6
7. Useful advice about important things in life……………	1	2	3	4	5	6
8. Help when I'm sick in bed……………………	1	2	3	4	5	6

H. **Healthy Days Core Module**	**Rating:** 1= Excellent 2= Very good 3= Good 4= Fair 5= Poor				
9. **Would you say that in general your health is…**	1	2	3	4	5
10. **Now, thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?** Number of days: _____ [ ] None [ ] Don't know/Not sure					
11. **Now, thinking about your mental health, which includes stress, depression and problems with emotions, for how many days during the past 30 days was your physical health not good?** Number of days: _____ [ ] None [ ] Don't know/Not sure					
12. **During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities such as self-care, work or recreation?** Number of days: _____ [ ] None [ ] Don't know/Not sure					

I. **Morisky Medication Scale:** **Individuals have identified several issues regarding their medication taking-behavior and we are interested in your experiences. There is no right or wrong answer. Please, answer each question based on your personal experience with your diabetes medication. Please, circle the correct number.**	**No**	**Yes**
1. Do you sometimes forget to take your diabetes medication?	0	1
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your diabetes medicine?	0	1
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	0	1
4. When you travel or leave home, do you sometimes forget to bring along your diabetes medication?	0	1
5. Did you take your diabetes medication yesterday?	0	1
6. When you feel like your diabetes is under control, do you sometimes stop taking your medicine?	0	1

APPENDIX E (continued)

7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?	0	1
8.How often do you have difficulty remembering to take all your medications? Please, circle the correct number.		
Never/Rarely		0
Once in a while		1
Sometimes		2
Usually		3
All the time		4

Receptivity to Exercise:		
J. What are the best experiences related to the current practice of exercise?		
1. I feel more relaxed; this exercise reduces my stress	**No**	Yes
2. I feel I have more energy	**No**	Yes
3. I feel it lowers my blood sugar	**No**	Yes
4. I sleep better	**No**	Yes
5. My sexual life has improved	**No**	Yes
6.I feel more motivated to exercise	**No**	Yes
7.I can move around more easily	**No**	Yes
8.I feel better in general	**No**	Yes
9.Other:	**No**	Yes
K.What are the worst experiences related to the current practice of exercise?		
10. Physical discomfort/pain/feet hurt	**No**	Yes
11. Difficulty of exercises	**No**	Yes
12. Boring	**No**	Yes
13 Stressful	**No**	Yes
14. Blood sugar went up	**No**	Yes
15. Tiredness	**No**	Yes
16. Other:	**No**	Yes
L. What things made it easy to maintain participation in classes?		
17. Instructor's modeling of exercises and verbal guidance	**No**	Yes
18. Class time	**No**	Yes
19. Class location	**No**	Yes
20. Availability of parking	**No**	Yes
21. Group class	**No**	Yes
22. Made friends in class	**No**	Yes
23. Other:	**No**	Yes
M. What things made it difficult to maintain participation in classes?		
24. Not enough instruction and modeling of exercises	**No**	Yes
25. Class time	**No**	Yes
26. Class location	**No**	Yes
27. Transportation	**No**	Yes
28. Too many people in class	**No**	Yes
29. Did not make friends in class	**No**	Yes
30. Other:	**No**	Yes

APPENDIX E (continued)

N. Intention to exercise regularly from now on?		
31. Will continue on my own	**No**	Yes
32. Will continue with video	**No**	Yes
33. Will join other class	**No**	Yes
34. Do not plan to exercise any more	**No**	Yes
35. Other:	**No**	Yes

O. During the last 7 days:
1. How many days did you practice your exercises at home?   ☐ 0   ☐1   ☐ 2   ☐ 3   ☐4   ☐5   ☐6   ☐7
2. On average, approximately how many minutes per day did you practice?   ☐ 5   ☐ 10   ☐15   ☐20   ☐ more than 20

P. Biomedical Outcomes:		
Height: **Weight:**		**BMI:**
A1C: **%**		
Blood pressure (1): / **mmHg**		**Average blood pressure:**
Blood pressure (2): / **mmHg**		
Blood pressure (3): / **mmHg**		_____ / _____ **mm Hg**

APPENDIX E (continued)

Screening #:
ID #:

University of Illinois at Chicago
Stress Reduction for
Elderly Hispanics Study
(StREHS)
-Phase 2-

Cuestionario Final

Nos gustaría hacerle algunas preguntas sobre sus antecedentes, su estado de salud, actividades de auto- cuidado, y sus niveles de estrés. Sus respuestas son confidenciales. Háganos saber si tiene alguna pregunta antes de comenzar.

Supervisado por: _____

Fecha: _____

A. Las preguntas siguientes son acerca de sus actividades de auto- cuidado durante los últimos 7 días. Si usted estuvo enfermo durante esos 7 días, piense en los últimos 7 días en los cuales usted no estuvo enfermo. Por favor, marque su respuesta con un círculo.								
Nutrición:								
1. ¿Cuántos de los últimos **siete días** ha seguido usted un plan de comida saludable?	0	1	2	3	4	5	6	7
2. En promedio, durante el último mes, ¿cuántos **días a la semana** ha seguido su plan de comida?	0	1	2	3	4	5	6	7
3. ¿Cuántos de los últimos **siete días** comió usted cinco o más porciones de fruta y vegetales?	0	1	2	3	4	5	6	7
4. ¿Cuántos de los últimos **siete días** comió usted comidas altas en grasa (por ejemplo, carne roja o productos lácteos sin desnatar)?	0	1	2	3	4	5	6	7
Actividad Física:								
5. ¿En cuántos de los últimos **siete días** participó usted en por lo menos 30 minutos de actividad física? (minutos totales de actividad continua, incluyendo caminar)	0	1	2	3	4	5	6	7
6. ¿En cuántos de los últimos **siete días** tomó usted parte en una sesión específica de ejercicio (como nadando, caminando, montando bicicleta) distinto al que hace en su casa o como parte del trabajo?	0	1	2	3	4	5	6	7
Análisis de Glucosa:								
7. ¿En cuántos de los últimos **siete días** se analizó su nivel de glucosa (azúcar en la sangre)?	0	1	2	3	4	5	6	7
8. ¿En cuántos de los últimos **siete días** se analizó su nivel de glucosa (azúcar en la sangre) el número de veces recomendado por su médico?	0	1	2	3	4	5	6	7
Medicamentos:								
9. Cambiaron sus medicinas en los últimos **tres meses**? ☐ Sí ☐ No								
10. Si cambiaron, cómo? ☐ Aumentaron ☐ Disminuyeron								

APPENDIX E (continued)

B. Escala de aflicción de la diabetes: Vivir con la diabetes a veces es difícil. Puede haber muchos problemas relacionados con la diabetes que puedan variar en severidad. Estos problemas varían desde molestias menores hasta dificultades muy graves. Enumeradas abajo hay 17 posibles problemas que las personas con diabetes puedan enfrentar. Considere qué tan problemáticas han sido para usted las siguientes situaciones durante el último mes, y por favor, marque con un círculo el número apropiado.	No es Problema		Problema Modera-do		Problema Grave		
52. Sentir que la diabetes está tomando mucha de mi energía mental y física todos los días.	0	1	2	3	4	5	6
53. Sentir que mi doctor no sabe lo suficiente acerca de la diabetes y el cuidado de la diabetes.	0	1	2	3	4	5	6
54. Sentirme que estoy enojada/o, con miedo y/o deprimida/o cuando pienso en vivir con diabetes.	0	1	2	3	4	5	6
55. Sentir que mi doctor no me da las recomendaciones suficientemente claras sobre cómo manejar mi diabetes.	0	1	2	3	4	5	6
56. Sentir que no me estoy analizando el nivel de azúcar en la sangre con suficiente frecuencia.	0	1	2	3	4	5	6
57. Sentir que no estoy logrando mantener mi régimen de cuidado de la diabetes.	0	1	2	3	4	5	6
58. Sentir que mis amigos o familiares no me dan suficiente apoyo en mis esfuerzos para cuidar mi diabetes (por ejemplo, planean actividades que chocan con mi horario, me animan a comer comidas inadecuadas para mí)	0	1	2	3	4	5	6
59. Sentir que la diabetes controla mi vida.	0	1	2	3	4	5	6
60. Sentir que mi doctor no toma en serio mis preocupaciones.	0	1	2	3	4	5	6
61. No sentirme segura/o de mi habilidad de manejar mi diabetes en la vida diaria.	0	1	2	3	4	5	6
62. Sentir que tendré complicaciones serias a largo plazo, sin importar lo que yo haga.	0	1	2	3	4	5	6
63. Sentir que no estoy siguiendo de cerca un buen régimen alimenticio.	0	1	2	3	4	5	6
64. Sentir que mis amigos o familiares no aprecian lo difícil que es vivir con la diabetes.	0	1	2	3	4	5	6
65. Sentirme sobrecargada/o por las necesidades que requiere vivir con la diabetes.	0	1	2	3	4	5	6
66. Sentir que no tengo un doctor que pueda visitar con frecuencia para tratar mi diabetes.	0	1	2	3	4	5	6
67. Sentir que no tengo la motivación suficiente para mantener el cuidado de mi diabetes.	0	1	2	3	4	5	6
68. Sentir que mis amigos o familiares no me dan el apoyo emocional que me gustaría tener.	0	1	2	3	4	5	6

C. Escala de la Percepción del Estrés: Las siguientes son preguntas acerca de lo que usted ha sentido y pensado durante el último mes. En cada caso, por favor indique con qué frecuencia usted se siente o piensa de cierta manera:	0= Nunca 1= Casi nunca 2= Algunas veces 3= Con alguna frecuencia 4= Muy a menudo				
1. En este último mes, ¿con qué frecuencia se ha molestado usted por algo que ocurrió inesperadamente?	0	1	2	3	4
2. En este último mes, ¿con qué frecuencia se ha sentido usted incapaz de controlar las cosas importantes en su vida?	0	1	2	3	4
3. En este último mes, ¿con qué frecuencia se ha sentido usted nervioso y "estresado/a"?	0	1	2	3	4
4. En este último mes, ¿con qué frecuencia se ha sentido usted con confianza en su habilidad para manejar sus problemas personales?	0	1	2	3	4
5. En este último mes, ¿con qué frecuencia ha sentido usted que las cosas le están saliendo como usted quiere?	0	1	2	3	4

APPENDIX E (continued)

6. En este último mes, ¿con qué frecuencia ha encontrado que usted no puede con todo lo que ha tenido que hacer?	0	1	2	3	4
7. En este último mes, ¿con qué frecuencia ha sido capaz de controlar irritaciones en su vida?	0	1	2	3	4
8. En este último mes, ¿con qué frecuencia ha sentido que usted está al día con todas las cosas?	0	1	2	3	4
9. En este último mes, ¿con qué frecuencia se ha enfurecido por cosas que estaban fuera de su control?	0	1	2	3	4
10. En este último mes, ¿con qué frecuencia ha sentido que las dificultades estaban aumentando tanto que usted no podría superarlas?	0	1	2	3	4

D. Inventario Hispano del Estrés para Inmigrantes: **Por favor, indique qué tan estresante es para usted cada una de las siguientes situaciones:**	1=Para nada estresante 2= Un poco 3= Algo estresante 4= Estresante 5= Extremadamente estresante				
1. Porque no sé suficiente inglés, ha sido difícil para mi interactuar con otras personas	1	2	3	4	5
2. Porque soy Latino/a se espera que yo trabaje más duro	1	2	3	4	5
3. Me he sentido presionado/a para aprender inglés	1	2	3	4	5
4. Porque soy Latino/a he tenido dificultad en encontrar el tipo de trabajo que yo quiero	1	2	3	4	5
5. He sido forzado/a a aceptar trabajos de bajo salario	1	2	3	4	5
6. He tenido que vigilar la calidad de mi trabajo para que otros no piensen que soy perezoso/a.	1	2	3	4	5
7. Porque no hablo bien el inglés, la gente me ha tratado mal.	1	2	3	4	5
8. Porque soy Latino/a ha sido difícil obtener promociones o aumentos de salario.	1	2	3	4	5
9. Mi ingreso no ha sido suficiente para sostener a mi familia o sostenerme a mí mismo.	1	2	3	4	5
10. Ha habido conflictos entre miembros de mi familia.	1	2	3	4	5
11. Ha habido violencia física entre miembros de mi familia.	1	2	3	4	5
12. He tenido peleas serias con miembros de mi familia.	1	2	3	4	5
13. He sentido que las ideas de mis hijos acerca de la sexualidad son muy liberales.	1	2	3	4	5
14. Mis hijos han hablado de irse de la casa.	1	2	3	4	5
15. Mis hijos han recibido malos reportes escolares (o bajas calificaciones).	1	2	3	4	5
16. Mi esposo/a y yo hemos estado en desacuerdo sobre como criar a nuestros hijos.	1	2	3	4	5
17. Mis hijos no han respetado mi autoridad de la forma que deberían.	1	2	3	4	5

E. Cuestionario de Actividad Física	1 = Mucho más activo 2 = Un poco más activo 3 = Más o menos lo mismo 4 = Un poco menos activo 5 = Mucho menos activo 6 = No aplica					
4. Cuando piensa en las cosas que hace en su trabajo, ¿cómo se calificaría en la cantidad de actividad física que usted hace comparada con otros de su misma edad y sexo?	1	2	3	4	5	6
2. Ahora, cuando piensa en las cosas que usted hace por fuera de su trabajo, ¿cómo se calificaría en la cantidad de actividad física que usted hace comparada con otros de su misma edad y sexo?	1	2	3	4	5	6
3. ¿Hace usted regularmente actividad extenuante o trabajo físico duro?	1	2	3	4	5	6
7. ¿Hace usted ejercicio o trabajo físico laboral por lo menos tres veces a la semana?	1	2	3	4	5	6

APPENDIX E (continued)

F. Escala de Auto-eficacia en Actividad Física: ¿Qué tan seguro está usted de que podría superar las siguientes barreras para hacer ejercicio?	1 = Muy inseguro 2 = Mas bien inseguro 3 = Mas bien seguro 4 = Muy seguro			
Yo puedo arreglármelas para hacer mis ejercicios……	1	2	3	4
1. …aun cuando tengo preocupaciones y problemas	1	2	3	4
2. … aun cuando caigo deprimido/a	1	2	3	4
3. …aun cuando me siento tenso/a	1	2	3	4
4. …aun cuando estoy cansado/a	1	2	3	4
5. …aun cuando estoy ocupado/a.	1	2	3	4

G. Cuestionario de Apoyo Social Funcional: Esta es una lista de algunas cosas que otras personas nos dan o hacen por nosotros, y que pueden ser de ayuda. Por favor, lea cada frase con cuidado y marque con un círculo el número que más se acerca a su situación.	1 = Tanto como me gustaría 2 = 3 = 4 = 5 = 6 = Mucho menos de lo que me gustaría					
Yo tengo………						
1. Personas que se preocupan por lo que me pasa a mí………………	1	2	3	4	5	6
2. Amor y afecto………………………..	1	2	3	4	5	6
10.Oportunidad de hablar con alguien acerca de mis problemas en el trabajo o con mis quehaceres de casa ……………………………..	1	2	3	4	5	6
11.Oportunidad de hablar con alguien en quien confío acerca de mis problemas personales y familiares ……………………………..	1	2	3	4	5	6
12.Oportunidad de hablar acerca de asuntos de dinero …………….	1	2	3	4	5	6
6. Invitaciones para salir y hacer cosas con otras personas…………..	1	2	3	4	5	6
7. Consejos útiles acerca de cosas importantes en mi vida ………….	1	2	3	4	5	6
8. Ayuda cuando estoy enfermo en cama …………………….	1	2	3	4	5	6

H. Módulo Central de los Días Saludables	1= Excelente 2= Muy buena 3= Buena 4= Más o menos 5= Pobre				
13.Usted diría que en general su salud es …	1	2	3	4	5
14.Ahora, pensando en su salud física, la cual incluye enfermedades y traumas físicos, ¿por cuántos días durante los pasados 30 días, su salud física no fue buena? Número de días: _____ [ ] Ninguno [ ] No sé/no estoy seguro/a					
15.Ahora, pensando en su salud mental, la cual incluye estrés, depresión y problemas emocionales, ¿por cuántos días durante los pasados 30 días, su salud mental no fue buena? Número de días: _____ [ ] Ninguno [ ] No sé/no estoy seguro/a					
16.Durante los pasados 30 días, ¿por cuántos días una pobre salud física o mental le impidió hacer sus actividades habituales tales como auto-cuidado, trabajo o recreación? Número de días: _____ [ ] Ninguno [ ] No sé/no estoy seguro/a					

APPENDIX E (continued)

I. Escala de Medicamentos de Morisky: Algunas personas han identificado problemas relacionados con el comportamiento al tomar medicamentos, y estamos interesados en su experiencia. No hay respuestas correctas o erradas. Por favor, responda cada pregunta con base en su experiencia personal con los medicamentos para su diabetes. Marque el número correcto.	No	Sí
2. ¿Olvida usted algunas veces tomar sus medicamentos para la diabetes?	0	1
2. Las personas algunas veces no toman sus medicinas por razones distintas al olvido. Pensando en las últimas dos semanas, ¿hubo algunos días en los que usted no tomó sus medicinas para la diabetes?	0	1
3. ¿Alguna vez ha reducido o ha dejado de tomar su medicina sin decirle a su doctor porque usted se sentía peor cuando la tomaba?	0	1
4. Cuando usted viaja o sale de casa, ¿se olvida a veces de llevar sus medicinas para la diabetes?	0	1
5.¿Tomo sus medicinas para la diabetes ayer?	0	1
6. Cuando usted siente que su diabetes está bajo control, ¿a veces deja de tomar su medicina?	0	1
7. Tomar medicinas todos los días es realmente inconveniente para algunas personas. ¿Se siente usted presionado/a a seguir su plan de tratamiento de su diabetes?	0	1
9. ¿Con qué frecuencia tiene usted dificultad para recordar tomar todas sus medicinas? Por favor, indique la respuesta correcta.		
Nunca/Raramente	0	
De vez en cuando	1	
Algunas veces	2	
Usualmente	3	
Todo el tiempo	4	

Receptividad al Ejercicio:		
J. ¿Cuáles son las mejores experiencias relacionadas con la práctica actual de ejercicio?		
1. Me siento más relajado/a; este ejercicio reduce mi estrés.	No	Sí
2. Siento que tengo más energía	No	Sí
3. Siento que me baja el azúcar en la sangre	No	Sí
4. Duermo mejor	No	Sí
5. Mi vida sexual ha mejorado	No	Sí
13. Me siento más motivado a hacer ejercicio	No	Sí
14. Me puedo mover más fácilmente	No	Sí
15. Me siento mejor en general	No	Sí
16. Otro:	No	Sí
K. ¿Cuáles son las peores experiencias relacionadas con la práctica actual de ejercicio?		
10. Incomodidad física/ dolor/ dolor de pies	No	Sí
11. La dificultad de los ejercicios	No	Sí
12. Es aburrido	No	Sí
13 Es estresante	No	Sí
14. Me subió el azúcar en la sangre	No	Sí
15. Siento cansancio con más frecuencia	No	Sí
16. Otro:	No	Sí
L. ¿Qué cosas hicieron fácil mantener la participación en las clases?		
17. El instructor modelaba los ejercicios y guiaba verbalmente	No	Sí
18. Las horas de clase	No	Sí
19. La ubicación del salón de clase	No	Sí
20. Había estacionamiento	No	Sí
21. Clases en grupo	No	Sí
22. Hice amigos en la clase	No	Sí
23. Otro:	No	Sí

APPENDIX E (continued)

M. ¿Qué cosas hicieron difícil mantener la participación en las clases?		
24. No hubo suficiente instrucción y modelado de los ejercicios	**No**	Sí
25. Las horas de clase	**No**	Sí
26. La ubicación del salón de clases	**No**	Sí
27. Transporte	**No**	Sí
28. Muchas personas en la clase	**No**	Sí
29. No hice amigos	**No**	Sí
30. Otro:	**No**	Sí
N. Intención de hacer ejercicio regularmente de ahora en adelante		
31. Voy a seguir por mi cuenta yo solo/a	**No**	Sí
32. Voy a seguir con video	**No**	Sí
33. Voy a tomar más clases	**No**	Sí
34. No planeo hacer más ejercicio	**No**	Sí
35. Otro:	**No**	Sí

O. Durante los últimos 7 días:
3. Cuántos días practicó usted los ejercicios en casa? ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7
4. En promedio, aproximadamente cuántos minutos al día practicó? ☐ 5 ☐ 10 ☐ 15 ☐ 20 ☐ más de 20

P. Resultados Bio-médicos:	
Estatura: **Peso:**	**IMC:**
A1C: **%**	
Presión arterial (1): / **mmHg**	**Promedio de presión arterial:**
Presión arterial (2): / **mmHg**	_____ / _____ **mm Hg**
Presión arterial (3): / **mmHg**	

APPENDIX E (continued)

Screening #:   ID #:

University of Illinois at Chicago
Stress Reduction for
Elderly Hispanics Study
(StREHS)
-Phase 2-

Post-test Questionnaire-2

We would like to ask you some questions about your health, self-care activities, levels of stress, and your experience during the exercise classes. Your answers are confidential. Let us know if you have any questions before we begin.

Staff Member: _____

Date of Completion: _____

A. Diabetes Self-care: **The questions that follow ask about your self-care activities during the past 7 days. If you were sick during those 7 days, think back to the last 7 days that you were not sick. Please circle your answer.**								
Diet:								
1. How many of the last SEVEN DAYS have you followed a healthful eating plan?	0	1	2	3	4	5	6	7
2. On average, over the past month, how many DAYS PER WEEK, have you followed your eating plan?	0	1	2	3	4	5	6	7
3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
4. On how many of the last SEVEN DAYS did you eat high fat foods (i.e., red meat, full fat dairy products, etc.)?	0	1	2	3	4	5	6	7
Exercise:								
5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (i.e., swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
Blood Sugar Testing:								
7. On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your heath care provider?	0	1	2	3	4	5	6	7
Medications:								
9. Did your medications change in the last **three months**? ☐ Yes ☐ No								
10. If yes, how? ☐ Increased ☐ Decreased								

APPENDIX E (continued)

B. Diabetes Distress Scale: Living with diabetes can sometimes be tough. There may be numerous problems and hassles concerning diabetes and they can greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas which people with diabetes may experience. Consider the degree to which each of the times may have distressed or bothered you during the past month and circle the appropriate number.	Not a problem		Moder ate proble m		Serious proble m		
69. Feeling that diabetes is taking up too much of my mental and physical energy every day	0	1	2	3	4	5	6
70. Feeling that my doctor doesn't know enough about diabetes and diabetes care	0	1	2	3	4	5	6
71. Feeling angry, scared and/or depressed when I think about living with diabetes	0	1	2	3	4	5	6
72. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes	0	1	2	3	4	5	6
73. Feeling that I am not testing my blood sugars frequently enough	0	1	2	3	4	5	6
74. Feeling that I am often failing with my diabetes regimen	0	1	2	3	4	5	6
75. Feeling that friends or family are not supportive enough of my self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods)	0	1	2	3	4	5	6
76. Feeling that diabetes controls my life	0	1	2	3	4	5	6
77. Feeling that my doctor doesn't take my concerns seriously enough	0	1	2	3	4	5	6
78. Not feeling confident in my day-to-day ability to manage diabetes	0	1	2	3	4	5	6
79. Feeling that I will end up with serious long-term complications, no matter what I do	0	1	2	3	4	5	6
80. Feeling that I am not sticking closely enough to a good meal plan	0	1	2	3	4	5	6
81. Feeling that friends or family don't appreciate how difficult living with diabetes can be	0	1	2	3	4	5	6
82. Feeling overwhelmed by the demands of living with diabetes.	0	1	2	3	4	5	6
83. Feeling that I don't have a doctor who I can see regularly about my diabetes	0	1	2	3	4	5	6
84. Not feeling motivated to keep up my diabetes self-management	0	1	2	3	4	5	6
85. Feeling that friends or family don't give me the emotional support that I would like	0	1	2	3	4	5	6

C. Perceived Stress Scale: These questions ask about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way:	Ratings: 0= Never 1= Almost never 2= Sometimes 3= Fairly often 4= Very often				
1. In the last month, how often have you been upset for something that happened unexpectedly?	0	1	2	3	4
2. In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3. In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5. In the last month, how often have you that things were going your way?	0	1	2	3	4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

APPENDIX E (continued)

D. Hispanic Stress Inventory-Immigrants: Please, rate the level of stressfulness of each of these incidents:	Ratings: 1=Not at all stressful 2= 3= 4= 5= Extremely stressful				
1. Because I do not know enough English, it has been difficult for me to interact with others	1	2	3	4	5
2. Because I am Latino I have been expected to work harder	1	2	3	4	5
3. I have felt pressured to learn English	1	2	3	4	5
4. Because I am Latino I have had difficulty finding the type of work I want.	1	2	3	4	5
5. I have been forced to accept low paying jobs.	1	2	3	4	5
6. I have had to watch the quality of my work so others do not think I am lazy.	1	2	3	4	5
7. Because of my poor English people have treated me badly.	1	2	3	4	5
8. Because I am Latino it has been hard to get promotion or salary raises.	1	2	3	4	5
9. My income has not been sufficient to support my family or myself.	1	2	3	4	5
10. There have been conflicts among members of my family.	1	2	3	4	5
11. There has been physical violence among members of my family.	1	2	3	4	5
12. I had serious arguments with family members.	1	2	3	4	5
13. I have felt that my children's ideas about sexuality are too liberal.	1	2	3	4	5
14. My children have talked about leaving home	1	2	3	4	5
15. My children have received bad school reports (or bad grades)	1	2	3	4	5
16. My spouse and I have disagreed on how to bring up our children.	1	2	3	4	5
17. My children have not respected my authority the way they should.	1	2	3	4	5

E. Physical Activity Questionnaire	Ratings: 1 = Much More Active 2 = Somewhat More Active 3 = About the Same 4 = Somewhat Less Active 5 = Much Less Active 6 = Not Applicable					
5. Thinking about the things you do at work, how would you rate yourself as to the amount of physical activity you get compared with others of your age and sex?	1	2	3	4	5	6
2. Now thinking about the things you do outside of work, how would you rate yourself as the amount of physical activity you get compared with others your age and sex?	1	2	3	4	5	6
3. Do you regularly engage in strenuous activity or hard physical labor?	1	2	3	4	5	6
8. Do you exercise or labor at least three times a week?	1	2	3	4	5	6

F. Physical activity self-efficacy scale: How sure are you that you could overcome the following barriers in performing your exercises?	Ratings: 1 = Very unsure 2 = Rather unsure 3 = Rather sure 4 = Very sure			
I can manage to perform my exercises……	1	2	3	4
1. …even when I have worries and problems	1	2	3	4
2. … even if I fell depressed	1	2	3	4
3. …even when I feel tense	1	2	3	4
4. …even when I am tired	1	2	3	4
5. …even when I am busy.	1	2	3	4

APPENDIX E (continued)

G. Functional Social Support Questionnaire: Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and circle the number that is closest to your situation.	Ratings: 1 = As much as I would like 2 = 3 = 4 = 5 = 6 = Much less than I would like					
I get………						
1. People who care what happens to me………………	1	2	3	4	5	6
2. Love and affection………………………..	1	2	3	4	5	6
17. Chances to talk to someone about problems at work or with my housework ………………………………..	1	2	3	4	5	6
18. Chances to talk to someone I trust about my personal and family problems……………………………..	1	2	3	4	5	6
3. Chances to talk about money matters………………………	1	2	3	4	5	6
6. Invitations to go out and do things with other people…………..	1	2	3	4	5	6
7. Useful advice about important things in life……………	1	2	3	4	5	6
8. Help when I'm sick in bed……………………	1	2	3	4	5	6

H. Healthy Days Core Module	Rating: 1= Excellent 2= Very good 3= Good 4= Fair 5= Poor				
17. **Would you say that in general your health is…**	1	2	3	4	5
18. **Now, thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?** Number of days: _____ [ ] None [ ] Don't know/Not sure					
19. **Now, thinking about your mental health, which includes stress, depression and problems with emotions, for how many days during the past 30 days was your physical health not good?** Number of days: _____ [ ] None [ ] Don't know/Not sure					
20. **During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities such as self-care, work or recreation?** Number of days: _____ [ ] None [ ] Don't know/Not sure					

I. Morisky Medication Scale: Individuals have identified several issues regarding their medication taking-behavior and we are interested in your experiences. There is no right or wrong answer. Please, answer each question based on your personal experience with your diabetes medication. Please, circle the correct number.	No	Yes
1.Do you sometimes forget to take your diabetes medication?	0	1
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your diabetes medicine?	0	1
3.Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	0	1
4. When you travel or leave home, do you sometimes forget to bring along your diabetes medication?	0	1
5.Did you take your diabetes medication yesterday?	0	1
6. When you feel like your diabetes is under control, do you sometimes stop taking your medicine?	0	1

APPENDIX E (continued)

7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your diabetes treatment plan?	0	1

8.How often do you have difficulty remembering to take all your medications? Please, circle the correct number.	
Never/Rarely	0
Once in a while	1
Sometimes	2
Usually	3
All the time	4

Receptivity to Exercise:		
J. What are the best experiences related to the current practice of exercise?		
1. I feel more relaxed; this exercise reduces my stress	**No**	Yes
2. I feel I have more energy	**No**	Yes
3. I feel it lowers my blood sugar	**No**	Yes
4. I sleep better	**No**	Yes
5. My sexual life has improved	**No**	Yes
6.I feel more motivated to exercise	**No**	Yes
7.I can move around more easily	**No**	Yes
8.I feel better in general	**No**	Yes
9.Other:	**No**	Yes
K.What are the worst experiences related to the current practice of exercise?		
10. Physical discomfort/pain/feet hurt	**No**	Yes
11. Difficulty of exercises	**No**	Yes
12. Boring	**No**	Yes
13 Stressful	**No**	Yes
14. Blood sugar went up	**No**	Yes
15. Tiredness	**No**	Yes
16. Other:	**No**	Yes
L. What things made it easy to maintain participation in classes?		
17. Instructor's modeling of exercises and verbal guidance	**No**	Yes
18. Class time	**No**	Yes
19. Class location	**No**	Yes
20. Availability of parking	**No**	Yes
21. Group class	**No**	Yes
22. Made friends in class	**No**	Yes
23. Other:	**No**	Yes
M. What things made it difficult to maintain participation in classes?		
24. Not enough instruction and modeling of exercises	**No**	Yes
25. Class time	**No**	Yes
26. Class location	**No**	Yes
27. Transportation	**No**	Yes
28. Too many people in class	**No**	Yes
29. Did not make friends in class	**No**	Yes
30. Other:	**No**	Yes

APPENDIX E (continued)

N. Intention to exercise regularly from now on?		
31. Will continue on my own	**No**	Yes
32. Will continue with video	**No**	Yes
33. Will join other class	**No**	Yes
34. Do not plan to exercise any more	**No**	Yes
35. Other:	**No**	Yes

O. During the last 7 days:
5. How many days did you practice your exercises at home?   ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7
6. On average, approximately how many minutes per day did you practice?   ☐ 5 ☐ 10 ☐ 15 ☐ 20 ☐ more than 20

P. Biomedical Outcomes:	
Height: **Weight:**	**BMI:**
A1C: **%**	
Blood pressure (1): / **mmHg**	**Average blood pressure:**
Blood pressure (2): / **mmHg**	
Blood pressure (3): / **mmHg**	_____ / _____ **mm Hg**

APPENDIX E (continued)

Screening #:
ID #:

University of Illinois at Chicago
**Stress Reduction for
Elderly Hispanics Study
(StREHS)
-Phase 2-**

Cuestionario Final-2

Nos gustaría hacerle algunas preguntas sobre sus antecedentes, su estado de salud, actividades de auto- cuidado, y sus niveles de estrés. Sus respuestas son confidenciales. Háganos saber si tiene alguna pregunta antes de comenzar.

Supervisado por: _____

Fecha: _____

A. Las preguntas siguientes son acerca de sus actividades de auto- cuidado durante los últimos 7 días. Si usted estuvo enfermo durante esos 7 días, piense en los últimos 7 días en los cuales usted no estuvo enfermo. Por favor, marque su respuesta con un círculo.								
Nutrición:								
11. ¿Cuántos de los últimos **siete días** ha seguido usted un plan de comida saludable?	0	1	2	3	4	5	6	7
12. En promedio, durante el último mes, ¿cuántos **días a la semana** ha seguido su plan de comida?	0	1	2	3	4	5	6	7
13. ¿Cuántos de los últimos **siete días** comió usted cinco o más porciones de fruta y vegetales?	0	1	2	3	4	5	6	7
14. ¿Cuántos de los últimos **siete días** comió usted comidas altas en grasa (por ejemplo, carne roja o productos lácteos sin desnatar)?	0	1	2	3	4	5	6	7
Actividad Física:								
15. ¿En cuántos de los últimos **siete días** participó usted en por lo menos 30 minutos de actividad física? (minutos totales de actividad continua, incluyendo caminar)	0	1	2	3	4	5	6	7
16. ¿En cuántos de los últimos **siete días** tomó usted parte en una sesión específica de ejercicio (como nadando, caminando, montando bicicleta) distinto al que hace en su casa o como parte del trabajo?	0	1	2	3	4	5	6	7
Análisis de Glucosa:								
17. ¿En cuántos de los últimos **siete días** se analizó su nivel de glucosa (azúcar en la sangre)?	0	1	2	3	4	5	6	7
18. ¿En cuántos de los últimos **siete días** se analizó su nivel de glucosa (azúcar en la sangre) el número de veces recomendado por su médico?	0	1	2	3	4	5	6	7
Medicamentos:								
9. Cambiaron sus medicinas en los últimos **tres meses**? ☐ Sí ☐ No								
10. Si cambiaron, cómo? ☐ Aumentaron ☐ Disminuyeron								

APPENDIX E (continued)

B. Escala de aflicción de la diabetes: Vivir con la diabetes a veces es difícil. Puede haber muchos problemas relacionados con la diabetes que puedan variar en severidad. Estos problemas varían desde molestias menores hasta dificultades muy graves. Enumeradas abajo hay 17 posibles problemas que las personas con diabetes puedan enfrentar. Considere qué tan problemáticas han sido para usted las siguientes situaciones durante el último mes, y por favor, marque con un círculo el número apropiado.	No es Problema		Problema Modera-do		Problema Grave		
86. Sentir que la diabetes está tomando mucha de mi energía mental y física todos los días.	0	1	2	3	4	5	6
87. Sentir que mi doctor no sabe lo suficiente acerca de la diabetes y el cuidado de la diabetes.	0	1	2	3	4	5	6
88. Sentirme que estoy enojada/o, con miedo y/o deprimida/o cuando pienso en vivir con diabetes.	0	1	2	3	4	5	6
89. Sentir que mi doctor no me da las recomendaciones suficientemente claras sobre cómo manejar mi diabetes.	0	1	2	3	4	5	6
90. Sentir que no me estoy analizando el nivel de azúcar en la sangre con suficiente frecuencia.	0	1	2	3	4	5	6
91. Sentir que no estoy logrando mantener mi régimen de cuidado de la diabetes.	0	1	2	3	4	5	6
92. Sentir que mis amigos o familiares no me dan suficiente apoyo en mis esfuerzos para cuidar mi diabetes (por ejemplo, planean actividades que chocan con mi horario, me animan a comer comidas inadecuadas para mí)	0	1	2	3	4	5	6
93. Sentir que la diabetes controla mi vida.	0	1	2	3	4	5	6
94. Sentir que mi doctor no toma en serio mis preocupaciones.	0	1	2	3	4	5	6
95. No sentirme segura/o de mi habilidad de manejar mi diabetes en la vida diaria.	0	1	2	3	4	5	6
96. Sentir que tendré complicaciones serias a largo plazo, sin importar lo que yo haga.	0	1	2	3	4	5	6
97. Sentir que no estoy siguiendo de cerca un buen régimen alimenticio.	0	1	2	3	4	5	6
98. Sentir que mis amigos o familiares no aprecian lo difícil que es vivir con la diabetes.	0	1	2	3	4	5	6
99. Sentirme sobrecargada/o por las necesidades que requiere vivir con la diabetes.	0	1	2	3	4	5	6
100. Sentir que no tengo un doctor que pueda visitar con frecuencia para tratar mi diabetes.	0	1	2	3	4	5	6
101. Sentir que no tengo la motivación suficiente para mantener el cuidado de mi diabetes.	0	1	2	3	4	5	6
102. Sentir que mis amigos o familiares no me dan el apoyo emocional que me gustaría tener.	0	1	2	3	4	5	6

C. Escala de la Percepción del Estrés: Las siguientes son preguntas acerca de lo que usted ha sentido y pensado durante el último mes. En cada caso, por favor indique con qué frecuencia usted se siente o piensa de cierta manera:	0= Nunca 1= Casi nunca 2= Algunas veces 3= Con alguna frecuencia 4= Muy a menudo				
1. En este último mes, ¿con qué frecuencia se ha molestado usted por algo que ocurrió inesperadamente?	0	1	2	3	4
2. En este último mes, ¿con qué frecuencia se ha sentido usted incapaz de controlar las cosas importantes en su vida?	0	1	2	3	4
3. En este último mes, ¿con qué frecuencia se ha sentido usted nervioso y "estresado/a"?	0	1	2	3	4
4. En este último mes, ¿con qué frecuencia se ha sentido usted con confianza en su habilidad para manejar sus problemas personales?	0	1	2	3	4
5. En este último mes, ¿con qué frecuencia ha sentido usted que las cosas le están saliendo como usted quiere?	0	1	2	3	4
6. En este último mes, ¿con qué frecuencia ha encontrado que usted no puede con todo lo que ha tenido que hacer?	0	1	2	3	4

APPENDIX E (continued)

7. En este último mes, ¿con qué frecuencia ha sido capaz de controlar irritaciones en su vida?	0	1	2	3	4
8. En este último mes, ¿con qué frecuencia ha sentido que usted está al día con todas las cosas?	0	1	2	3	4
9. En este último mes, ¿con qué frecuencia se ha enfurecido por cosas que estaban fuera de su control?	0	1	2	3	4
10. En este último mes, ¿con qué frecuencia ha sentido que las dificultes estaban aumentando tanto que usted no podría superarlas?	0	1	2	3	4

D. Inventario Hispano del Estrés para Inmigrantes: Por favor, indique qué tan estresante es para usted cada una de las siguientes situaciones:	1=Para nada estresante 2= Un poco 3= Algo estresante 4= Estresante 5= Extremadamente estresante				
1. Porque no sé suficiente inglés, ha sido difícil para mi interactuar con otras personas	1	2	3	4	5
2. Porque soy Latino/a se espera que yo trabaje más duro	1	2	3	4	5
3. Me he sentido presionado/a para aprender inglés	1	2	3	4	5
4. Porque soy Latino/a he tenido dificultad en encontrar el tipo de trabajo que yo quiero	1	2	3	4	5
5. He sido forzado/a a aceptar trabajos de bajo salario	1	2	3	4	5
6. He tenido que vigilar la calidad de mi trabajo para que otros no piensen que soy perezoso/a.	1	2	3	4	5
7. Porque no hablo bien el inglés, la gente me ha tratado mal.	1	2	3	4	5
8. Porque soy Latino/a ha sido difícil obtener promociones o aumentos de salario.	1	2	3	4	5
9. Mi ingreso no ha sido suficiente para sostener a mi familia o sostenerme a mí mismo.	1	2	3	4	5
10. Ha habido conflictos entre miembros de mi familia.	1	2	3	4	5
11. Ha habido violencia física entre miembros de mi familia.	1	2	3	4	5
12. He tenido peleas serias con miembros de mi familia.	1	2	3	4	5
13. He sentido que las ideas de mis hijos acerca de la sexualidad son muy liberales.	1	2	3	4	5
14. Mis hijos han hablado de irse de la casa.	1	2	3	4	5
15. Mis hijos han recibido malos reportes escolares (o bajas calificaciones).	1	2	3	4	5
16. Mi esposo/a y yo hemos estado en desacuerdo sobre como criar a nuestros hijos.	1	2	3	4	5
17. Mis hijos no han respetado mi autoridad de la forma que deberían.	1	2	3	4	5

E. Cuestionario de Actividad Física	1 = Mucho más activo 2 = Un poco más activo 3 = Más o menos lo mismo 4 = Un poco menos activo 5 = Mucho menos activo 6 = No aplica					
6. Cuando piensa en las cosas que hace en su trabajo, ¿cómo se calificaría en la cantidad de actividad física que usted hace comparada con otros de su misma edad y sexo?	1	2	3	4	5	6
2. Ahora, cuando piensa en las cosas que usted hace por fuera de su trabajo, ¿cómo se calificaría en la cantidad de actividad física que usted hace comparada con otros de su misma edad y sexo?	1	2	3	4	5	6
3. ¿Hace usted regularmente actividad extenuante o trabajo físico duro?	1	2	3	4	5	6
9. ¿Hace usted ejercicio o trabajo físico laboral por lo menos tres veces a la semana?	1	2	3	4	5	6

APPENDIX E (continued)

F. Escala de Auto-eficacia en Actividad Física: ¿Qué tan seguro está usted de que podría superar las siguientes barreras para hacer ejercicio?	1 = Muy inseguro 2 = Mas bien inseguro 3 = Mas bien seguro 4 = Muy seguro			
Yo puedo arreglármelas para hacer mis ejercicios……	1	2	3	4
1. …aun cuando tengo preocupaciones y problemas	1	2	3	4
2. … aun cuando caigo deprimido/a	1	2	3	4
3. …aun cuando me siento tenso/a	1	2	3	4
4. …aun cuando estoy cansado/a	1	2	3	4
5. …aun cuando estoy ocupado/a.	1	2	3	4

H. Cuestionario de Apoyo Social Funcional: Esta es una lista de algunas cosas que otras personas nos dan o hacen por nosotros, y que pueden ser de ayuda. Por favor, lea cada frase con cuidado y marque con un círculo el número que más se acerca a su situación.	1 = Tanto como me gustaría 2 = 3 = 4 = 5 = 6 = Mucho menos de lo que me gustaría					
Yo tengo……….						
1. Personas que se preocupan por lo que me pasa a mí………………	1	2	3	4	5	6
2. Amor y afecto………………………..	1	2	3	4	5	6
19. Oportunidad de hablar con alguien acerca de mis problemas en el trabajo o con mis quehaceres de casa ………………………………..	1	2	3	4	5	6
20. Oportunidad de hablar con alguien en quien confío acerca de mis problemas personales y familiares ……………………………..	1	2	3	4	5	6
21. Oportunidad de hablar acerca de asuntos de dinero …………….	1	2	3	4	5	6
6. Invitaciones para salir y hacer cosas con otras personas…………..	1	2	3	4	5	6
7. Consejos útiles acerca de cosas importantes en mi vida ………….	1	2	3	4	5	6
8. Ayuda cuando estoy enfermo en cama …………………….	1	2	3	4	5	6

H. Módulo Central de los Días Saludables	1= Excelente 2= Muy buena 3= Buena 4= Más o menos 5= Pobre				
21. Usted diría que en general su salud es …	1	2	3	4	5

22. Ahora, pensando en su salud física, la cual incluye enfermedades y traumas físicos, ¿por cuántos días durante los pasados 30 días, su salud física no fue buena?
Número de días: _____   [ ] Ninguno   [ ] No sé/no estoy seguro/a

23. Ahora, pensando en su salud mental, la cual incluye estrés, depresión y problemas emocionales, ¿por cuántos días durante los pasados 30 días, su salud mental no fue buena?
Número de días: _____   [ ] Ninguno   [ ] No sé/no estoy seguro/a

24. Durante los pasados 30 dias, ¿por cuántos días una pobre salud física o mental le impidió hacer sus actividades habituales tales como auto-cuidado, trabajo o recreación?
Número de días: _____   [ ] Ninguno   [ ] No sé/no estoy seguro/a

APPENDIX E (continued)

I. Escala de Medicamentos de Morisky: **Algunas personas han identificado problemas relacionados con el comportamiento al tomar medicamentos, y estamos interesados en su experiencia. No hay respuestas correctas o erradas. Por favor, responda cada pregunta con base en su experiencia personal con los medicamentos para su diabetes. Marque el número correcto.**	No	Sí
3. ¿Olvida usted algunas veces tomar sus medicamentos para la diabetes?	0	1
2. Las personas algunas veces no toman sus medicinas por razones distintas al olvido. Pensando en las últimas dos semanas, ¿hubo algunos días en los que usted no tomó sus medicinas para la diabetes?	0	1
3. ¿Alguna vez ha reducido o ha dejado de tomar su medicina sin decirle a su doctor porque usted se sentía peor cuando la tomaba?	0	1
4. Cuando usted viaja o sale de casa, ¿se olvida a veces de llevar sus medicinas para la diabetes?	0	1
5.¿Tomo sus medicinas para la diabetes ayer?	0	1
6. Cuando usted siente que su diabetes está bajo control, ¿a veces deja de tomar su medicina?	0	1
7. Tomar medicinas todos los días es realmente inconveniente para algunas personas. ¿Se siente usted presionado/a a seguir su plan de tratamiento de su diabetes?	0	1
10.¿Con qué frecuencia tiene usted dificultad para recordar tomar todas sus medicinas? Por favor, indique la respuesta correcta.		
Nunca/Raramente	0	
De vez en cuando	1	
Algunas veces	2	
Usualmente	3	
Todo el tiempo	4	

Receptividad al Ejercicio:		
J. ¿Cuáles son las mejores experiencias relacionadas con la práctica actual de ejercicio?		
1. Me siento más relajado/a; este ejercicio reduce mi estrés.	**No**	Sí
2. Siento que tengo más energía	**No**	Sí
3. Siento que me baja el azúcar en la sangre	**No**	Sí
4. Duermo mejor	**No**	Sí
5. Mi vida sexual ha mejorado	**No**	Sí
22.Me siento más motivado a hacer ejercicio	**No**	Sí
23.Me puedo mover más fácilmente	**No**	Sí
24.Me siento mejor en general	**No**	Sí
25.Otro:	**No**	Sí
K. ¿Cuáles son las peores experiencias relacionadas con la práctica actual de ejercicio?		
10. Incomodidad física/ dolor/ dolor de pies	**No**	Sí
11. La dificultad de los ejercicios	**No**	Sí
12. Es aburrido	**No**	Sí
13 Es estresante	**No**	Sí
14. Me subió el azúcar en la sangre	**No**	Sí
15. Siento cansancio con más frecuencia	**No**	Sí
16. Otro:	**No**	Sí
L. ¿Qué cosas hicieron fácil mantener la participación en las clases?		
17. El instructor modelaba los ejercicios y guiaba verbalmente	**No**	Sí
18. Las horas de clase	**No**	Sí
19. La ubicación del salón de clase	**No**	Sí
20. Había estacionamiento	**No**	Sí
21. Clases en grupo	**No**	Sí
22. Hice amigos en la clase	**No**	Sí
23. Otro:	**No**	Sí

APPENDIX E (continued)

M. ¿Qué cosas hicieron difícil mantener la participación en las clases?		
24. No hubo suficiente instrucción y modelado de los ejercicios	**No**	Sí
25. Las horas de clase	**No**	Sí
26. La ubicación del salón de clases	**No**	Sí
27. Transporte	**No**	Sí
28. Muchas personas en la clase	**No**	Sí
29. No hice amigos	**No**	Sí
30. Otro:	**No**	Sí
N. Intención de hacer ejercicio regularmente de ahora en adelante		
31. Voy a seguir por mi cuenta yo solo/a	**No**	Sí
32. Voy a seguir con video	**No**	Sí
33. Voy a tomar más clases	**No**	Sí
34. No planeo hacer más ejercicio	**No**	Sí
35. Otro:	**No**	Sí

O. Durante los últimos 7 días:
7. Cuántos días practicó usted los ejercicios en casa?   □ 0   □1   □ 2   □ 3   □4   □5   □6   □7
8. En promedio, aproximadamente cuántos minutos al día practicó?   □ 5   □ 10   □15   □20   □ más de 20

P. Resultados Bio-médicos:	
Estatura: **Peso:**	**IMC:**
A1C: **%**	
Presión arterial (1): / **mmHg**	**Promedio de presión arterial:**
Presión arterial (2): / **mmHg**	_____ / _____ **mm Hg**
Presión arterial (3): / **mmHg**	

APPENDIX F

Screening #: ID #:	University of Illinois at Chicago **Stress Reduction for** **Elderly Hispanics Study** **(StREHS)**

Follow-Up Questionnaire

Receptivity:		
A. What are the best experiences related to the practice of Tai Chi?		
1. I feel more relaxed; this exercise reduces my stress	**No**	Yes
2. I feel I have more energy	**No**	Yes
3. I feel it lowers my blood sugar	**No**	Yes
4. I sleep better	**No**	Yes
5. My sexual life has improved	**No**	Yes
6. I feel more motivated to exercise	**No**	Yes
7. I can move around more easily	**No**	Yes
8. I feel better in general	**No**	Yes
9. Other:	**No**	Yes
B. What are the worst experiences related to the practice of Tai Chi?		
10. Physical discomfort/pain/feet hurt	**No**	Yes
11. Difficulty of exercises	**No**	Yes
12. Boring	**No**	Yes
13 Stressful	**No**	Yes
14. Blood sugar went up	**No**	Yes
15. Tiredness	**No**	Yes
16. Other:	**No**	Yes
C. What things made it easy to maintain participation in classes?		
17. Instructor's modeling of exercises and verbal guidance	**No**	Yes
18. Class time	**No**	Yes
19. Class location	**No**	Yes
20. Availability of parking	**No**	Yes
21. Group class	**No**	Yes
22. Made friends in class	**No**	Yes
23. Other:	**No**	Yes
D. What things made it difficult to maintain participation in classes?		
24. Not enough instruction and modeling of exercises	**No**	Yes
25. Class time	**No**	Yes
26. Class location	**No**	Yes
27. Transportation	**No**	Yes
28. Too many people in class	**No**	Yes
29. Did not make friends in class	**No**	Yes
30. Other:	**No**	Yes

APPENDIX F (continued)

E. Intention to practice Tai Chi regularly from now on?		
31. Will continue on my own	**No**	Yes
32. Will continue with video	**No**	Yes
33. Will join other class	**No**	Yes
34. Do not plan to exercise any more	**No**	Yes
35. Other:	**No**	Yes

We would like to ask you some questions about your practice of exercise, and your experience during the exercise classes. Your answers are confidential. Let us know if you have any questions before we begin.

Staff Member: _____**Date of Completion:** _____

F. During the last 7 days:
9. How many days did you practice your exercises at home?   ☐ 0   ☐1   ☐ 2   ☐ 3   ☐4   ☐5   ☐6   ☐7
10.   On average, approximately how many minutes per day did you practice?   ☐ 5   ☐ 10   ☐15   ☐20   ☐ more than 20

APPENDIX F (continued)

Screening #: ID #:	University of Illinois at Chicago **Stress Reduction for Elderly Hispanics Study (StREHS)**

Cuestionario de Seguimiento

Nos gustaría hacerle algunas preguntas sobre su práctica de ejercicio y su experiencia durante las clases. Sus respuestas son confidenciales. Háganos saber si tiene alguna pregunta antes de comenzar.

Supervisado por: _____

Fecha: _____

Receptividad:		
A. ¿Cuáles son las mejores experiencias relacionadas con la práctica actual de Tai Chi?		
1. Me siento más relajado/a; este ejercicio reduce mi estrés.	**No**	Sí
2. Siento que tengo más energía	**No**	Sí
3. Siento que me baja el azúcar en la sangre	**No**	Sí
4. Duermo mejor	**No**	Sí
5. Mi vida sexual ha mejorado	**No**	Sí
6. Me siento más motivado a hacer ejercicio	**No**	Sí
7. Me puedo mover más fácilmente	**No**	Sí
8. Me siento mejor en general	**No**	Sí
9. Otro:	**No**	Sí
B. ¿Cuáles son las peores experiencias relacionadas con la práctica actual de Tai Chi?		
10. Incomodidad física/ dolor/ dolor de pies	**No**	Sí
11. La dificultad de los ejercicios	**No**	Sí
12. Es aburrido	**No**	Sí
13 Es estresante	**No**	Sí
14. Me subió el azúcar en la sangre	**No**	Sí
15. Siento cansancio con más frecuencia	**No**	Sí
16. Otro:	**No**	Sí
C. ¿Qué cosas hicieron fácil mantener la participación en las clases?		
17. El instructor modelaba los ejercicios y guiaba verbalmente	**No**	Sí
18. Las horas de clase	**No**	Sí
19. La ubicación del salón de clase	**No**	Sí
20. Había estacionamiento	**No**	Sí
21. Clases en grupo	**No**	Sí
22. Hice amigos en la clase	**No**	Sí
23. Otro:	**No**	Sí

APPENDIX F (continued)

D. ¿Qué cosas hicieron difícil mantener la participación en las clases?		
24. No hubo suficiente instrucción y modelado de los ejercicios	**No**	Sí
25. Las horas de clase	**No**	Sí
26. La ubicación del salón de clases	**No**	Sí
27. Transporte	**No**	Sí
28. Muchas personas en la clase	**No**	Sí
29. No hice amigos	**No**	Sí
30. Otro:	**No**	Sí
E. Intención de practicar Tai Chi regularmente de ahora en adelante		
31. Voy a seguir por mi cuenta yo solo/a	**No**	Sí
32. Voy a seguir con video	**No**	Sí
33. Voy a tomar más clases	**No**	Sí
34. No planeo hacer más ejercicio	**No**	Sí
35. Otro:	**No**	Sí

F. Durante los últimos 7 días:
11.   Cuántos días practicó usted los ejercicios en casa?
☐ 0   ☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6   ☐ 7
12.   En promedio, aproximadamente cuántos minutos al día practicó?
☐ 5   ☐ 10   ☐ 15   ☐ 20   ☐ más de 20

APPENDIX G

Approval Notice
Initial Review (Response To Modifications)

December 22, 2010; *Revised*

Amparo Del Castillo, MD
Institute for Health Research and Policy
1747 W. Roosevelt Road, Room 555
M/C 275
Chicago, IL
Phone: (312) 996-0683 / Fax: (312) 413-4750

RE: Protocol # 2010-0816
        "Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes"

Dear Dr. Castillo:

Revision: The statement regarding the waiver of signed consent was inadvertently omitted in the initial approval letter.

Your Initial Review (Response To Modifications) was reviewed and approved by Members of IRB #2 by the Expedited review process on December 8, 2010. You may now begin your research

Please note the following information about your approved research protocol:

Protocol Approval Period: December 8, 2010 - December 7, 2011
Approved Subject Enrollment #:   30
Additional Determinations for Research Involving Minors: These determinations have not been made for this study since it has not been approved for enrollment of minors.
Performance Sites: UIC
Sponsor: National Institutes of Health
PAF#:   2009-02182
Grant/Contract No: P30AG022849-07
Grant/Contract Title: Roybal Center for Translational Research on Aging-stress reduction with Tai Chi for elderly Hispanics with diabetes.
Research Protocol(s):

   a) Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes, Version #2, November 8, 2010

Recruitment Material(s):

   a) Newsletter Blurb -Spanish (English), Version 1 - 09-23-10

APPENDIX G (continued)

    b) Newsletter Blurb (Spanish), Version 1, 09-23-10
    c) Recruitment/Screening Script- English, Version 2- 11/08/10
    d) Recruitment/Screening Script- Spanish, Version 2- 11/08/10
    e) Flyer- version 1 (English)- 9/23/10- UIC
    f) Flyer- version 1 (Spanish) - 9/23/10
    g) Screening Questionnaire-English, Version 1 - 09/23/2010
    h) Screening Questionnaire- Spanish, Version 1 - 09/23/10

Informed Consent(s):

    a) Tai Chi for Older Hispanics Focus Groups (English), Version 3, November 30, 2010
    b) Tai Chi for Older Hispanics Focus Groups (Spanish), Version 3, November 30, 2010
    c) Waiver of Signed Consent Document granted under 45 CFR 46.117 for eligibility screening only; *Revised*

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific categories:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.,
(7) Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
09/30/2010	Initial Review	Expedited	10/04/2010	Modifications Required
11/09/2010	Response To Modifications	Expedited	11/16/2010	Modifications Required
12/02/2010	Response To Modifications	Expedited	12/08/2010	Approved

Please remember to:

→ Use your **research protocol number** (2010-0816) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
"UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 355-2939. Please send any
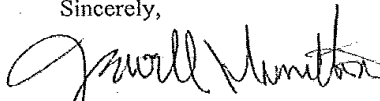
APPENDIX G (continued)

correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

J/well Hamilton, MSW
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects

Enclosure(s):

1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
2. **Informed Consent Document(s):**
   a) Tai Chi for Older Hispanics Focus Groups (English), Version 3, November 30, 2010
   b) Tai Chi for Older Hispanics Focus Groups (Spanish), Version 3, November 30, 2010
3. **Recruiting Material(s):**
   a) Newsletter Blurb -Spanish (English), Version 1 - 09-23-10
   b) Newsletter Blurb (Spanish), Version 1, 09-23-10
   c) Recruitment/Screening Script- English, Version 2- 11/08/10
   d) Recruitment/Screening Script- Spanish, Version 2- 11/08/10
   e) Flyer- version 1 (English)- 9/23/10- UIC
   f) Flyer- version 1 (Spanish) - 9/23/10
   g) Screening Questionnaire-English, Version 1 - 09/23/2010
   h) Screening Questionnaire- Spanish, Version 1 - 09/23/10

cc: Robin J. Mermelstein, Institute for Health Research and Policy, M/C 275
        Laurie Ruggiero, Faculty Sponsor, Institute for Health Research and Policy, M/C 275
        OVCR Administration, M/C 672

APPENDIX G (continued)

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice - *REVISED*
Amendment to Research Protocol and Consent Documents – Expedited Review
UIC Amendment # 1

June 27, 2012

Amparo Del Castillo, MD
Institute for Health Research and Policy
1747 W. Roosevelt Road, Room 555
M/C 275
Chicago, IL
Phone: (312) 413-9490 / Fax: (312) 996-3212

RE: **Protocol # 2010-0816**
         "Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes"

Dear Dr. Castillo:

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and consent forms under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

Please note that OPRS/IRB acknowledges the receipt of an IRB Authorization Agreement (IAA) for Centro Communitario Juan Diego (FWA #00007800) signed by the Director. As the IRB has approved the intent to add Centro Communitario Juan Diego, the IAA will be held until the status of the IAA can be verified and then routed to the authorized signatory official at UIC for completion. Once the IAA has been counter-signed and completed by UIC, this approval letter will be revised to indicate that the research may commence at Centro Communitario Juan Diego and that organization will be listed under the "Performance Site" section of this approval letter.

Amendment Approval Date: June 19, 2012
Amendment:
    Summary: UIC Amendment #1 (Response to Modifications), submitted 12 June 2012, is an investigator-initiated amendment regarding the following: (1) adding Aim 2 and 3 of the study incorporating feedback from Aim 1 focus groups; Aim 2 and 3 consist of assessing the impact

of Tai Chi on A1C levels, psychosocial stress, and blood pressure; activities include a randomized trial of Tai Chi among elderly Hispanics with Type 2 Diabetes (T2D), comparing Tai Chi with stretching/calisthenics, evaluating statistical trends among participants by group on A1C levels, psychosocial stress levels and blood pressure; each Tai Chi or stretching class lasts 60 minutes, and is conducted twice a week for 12 weeks; both classes are facilitated by certified bilingual instructors; participants will complete baseline and post-test questionnaires, a short survey at six weeks after baseline, blood draw will be conducted and assessed at baseline by the Principal Investigator, three blood measures will be conducted after the participant has rested for five minutes and ten minutes, and the average value will be recorded; height and weight will be recorded at baseline; participants will receive $20 each for completing the baseline and post-test assessments, for a total of $40; no compensation will be provided for completing the six-week assessment but participants will be given the opportunity to win small gifts such as a pedometer (revised Initial Review Application, version 3, 6/8/2012); increasing the number of participants per group to 35 for a total of 70 participants in this Aim; narrowing inclusion criteria to adults 50-80 years old, who can practice exercise, who do not have any co-morbidities that could increase risk (except for hypertension equal or less than 160/100 mm Hg) or would interfere with physical activity, who do not have self-reported substance abuse, who have received formal training in yoga, Tai Chi, or relaxation techniques, who will not be travelling within four months after enrollment, and who agree to sign the consent and authorization; a two-stage screening consisting of an initial eligibility screening and assessing risk via an adapted EASY instrument and medical screening, if necessary (revised Research Protocol, version 4, 6/11/2012; Baseline Questionnaire, English + Spanish, version 1, 4/21/2012 + 4/24/2012; Post-test Questionnaire, English + Spanish, version 1, 4/24/2012; 6 Week Questionnaire, English + Spanish, version 1, 4/21/2012 + 4/24/2012; Appendix M, version 3, 6/11/2012; Pilot Project Core with Budget);
(2) addition of Chicago Family Health Center, Centro Communitario Juan Diego, Villa Guadalupe Senior Services, and Creation's Touch as research sites (Chicago Family Health Center IRB Authorization Agreement, 3/26/2012; Centro Communitario Juan Diego, 4/20/2012; Villa Guadalupe Senior Services, 5/16/2012; and Creation's Touch, 5/27/2012);
(3) adding Beatrice DeFranco, Maria del Carmen Garcia, and Guadalupe Ramirez as key research personnel (Appendix P); and
(4) submission of recruitment and consent documents reflecting the above (Flyer, English + Spanish, version 2, 3/23/2012; Newsletter Blurb, English + Spanish, version 2, 3/23/2012; Recruitment/Screening Script, English + Spanish, version 4, 6/11/2012; CFHC Invitation Letter, version 1, 4/30/2012; Initial Screening Form, English + Spanish, version 2, 4/21/2012; Second Screening Form, English + Spanish, version 1, 4/24/2012; Physician's Letter, version 1, 4/30/2012; Exercise and Screening for You, 11/15/2007, 4/3/2008; Consent, English + Spanish, version 5, 6/8/2012; translator's statement).

Approved Subject Enrollment #:	70
Performance Sites:	UIC, *REVISED* - Villa Guadalupe Senior Services, Inc., Chicago Family Health Center, Inc., Creation's Touch
Sponsor:	National Institutes of Health
PAF#:	2009-02182
Grant/Contract No:	P30AG022849-07
Grant/Contract Title:	Roybal Center for Translational Research on Aging-stress reduction with Tai Chi for elderly Hispanics with diabetes.

APPENDIX G (continued)

2010-0816   Page 3 of 4   6/27/2012

Research Protocol:
   a) Stress Reduction with Tai Chi in Elderly Hispanics with Diabetes; Version 4; 06/11/2012
Recruiting Materials:
   a) Flyer (English); Version 2; 03/23/2012
   b) Flyer (Spanish); Version 2; 03/23/2012
   c) Newsletter Blurb (English); Version 2; 03/23/2012
   d) Newsletter Blurb (Spanish); Version 2; 03/23/2012
   e) Initial Screening Form (English); Version 2; 04/21/2012
   f) Initial Screening Form (Spanish); Version 2; 04/21/2012
   g) Second Screening Form (English); Version 1; 04/24/2012
   h) Second Screening Form (Spanish); Version 1; 04/24/2012
   i) CFHC Invitation Letter (English); Version 1; 04/30/2012
   j) Physician's Letter Stress Reduction Study; Version 1; 04/30/2012
   k) Recruitment/Screening Script (English); Version 4; 06/11/2012
   l) Recruitment Script (Spanish); Version 4; 06/11/2012
Informed Consents:
   a) Stress Reduction for Elderly Hispanics Study (English); Version 5; 06/08/2012
   b) Stress Reduction for Elderly Hispanics Study (Spanish); Version 5; 06/08/2012
   c) A waiver of documentation of informed consent has been granted under 46 CFR 46.117 for
       recruitment purposes only (minimal risk; verbal consent will be obtained for
       screening/eligibility purposes; written consent will be obtained at enrollment)

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
05/08/2012	Amendment	Expedited	05/14/2012	Modifications Required
06/12/2012	Response To Modifications	Expedited	06/19/2012	Approved

Please be sure to:

→ **Use only the IRB-approved and stamped consent documents when enrolling subjects.**

→ Use your research protocol number (2010-0816) on any documents or correspondence with the
IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
"UIC Investigator Responsibilities, Protection of Human Research Subjects"

**Please note that the UIC IRB #2 has the right to ask further questions, seek additional
information, or monitor the conduct of your research and the consent process.**

**Please be aware that if the scope of work in the grant/project changes, the protocol must be
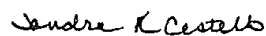amended and approved by the UIC IRB before the initiation of the change.**

APPENDIX G (continued)

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 996-2014. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Sandra Costello
Assistant Director, IRB # 2
Office for the Protection of Research Subjects

Enclosures:

1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
2. **Data Security Enclosure**
3. **Informed Consent Documents:**
   a) *Forwarded with original approval letter*
4. **Recruiting Materials:**
   a) *Forwarded with original approval letter*

cc: Laurie Ruggiero (faculty advisor), Institute for Health Research and Policy, M/C 275
       Robin J. Mermelstein, Institute for Health Research and Policy, M/C 275

APPENDIX G (continued)

U N I V E R S I T Y   O F   I L L I N O I S
A T   C H I C A G O

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Amendment to Research Protocol and/or Consent Document – Expedited Review
UIC Amendment # 2

August 27, 2012

Amparo Del Castillo, MD
Institute for Health Research and Policy
1747 W. Roosevelt Road, Room 555
M/C 275
Chicago, IL
Phone: (312) 413-9490 / Fax: (312) 996-3212

RE: **Protocol # 2010-0816**
          "Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes"

> *Please note that the Amendment #2 approval letter has been revised on August 27, 2012 to reflect the approval of the IRB Authorization Agreement (IAA) by the authorized official at UIC (the Vice Chancellor for Research) between UIC and the Centro Comunitario Juan Diego. The letter has also been revised to list Centro Comunitario Juan Diego under the "Performance Sites" section of the approval letter. The research may now commence at the Centro Comunitario Juan Diego. Please find the original IAA enclosed with this revised approval letter.*

Dear Dr. Castillo:

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and/or consent form under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

Amendment Approval Date: August 13, 2012
Amendment:
    Summary: UIC Amendment #2, dated 6 August 2012 and submitted to OPRS 9 August 2012, is an investigator-initiated amendment regarding the following:
    (1) changing experimental procedures to provide the intervention group with Tai Chi instruction the first 12 weeks after randomization, while the control group will receive only a

Phone: 312-996-1711   http://www.uic.edu/depts/ovcr/oprs/   FAX: 312-413-2929

minimal intervention consisting of brochures and other printed information regarding diabetes care, physical activity, and stress reduction; during the intervention phase, the control (health advice) will be contacted over the phone once per month to maintain contact and remind the control participants of the benefits of exercise; after the intervention phase, the control group will cross over to receive a delayed series of Tai Chi instruction; the original intervention group will be followed up with 12 weeks after the end of the intervention to assess their maintenance of exercise practice; assessments during the initial intervention period will be done as originally planned and approved, at baseline and post-test for both the Tai Chi and control groups simultaneously, and will include A1C, blood pressure, and BMI as well as behavioral questionnaires; the 6-week questionnaire will also be given to both groups; assessments for the cross-over control group will be done at the end of their 12 weeks of Tai Chi instruction, at the same time that the original Tai Chi group is assessed on the maintenance of their exercise practice; these last assessments for the cross-over and original Tai Chi groups will be on the acceptability, adherence, and intention to practice but will not include A1C, blood pressure, or BMI due to budget limitations; Aim 3 of the study is changed to assess the impact of Tai Chi on A1C, psychosocial stress, and blood pressure levels by implementing a randomized trial of Tai Chi among elderly Hispanics with Type 2 diabetes, comparing Tai Chi versus advice on health and exercise; evaluating statistical trends among participants by group on A1C levels, psychosocial stress, and blood pressure levels; there will be no changes in screening procedures or number of participants (revised Initial Review application, version 4, 8/6/2012; revised Research Protocol, version 5, 8/6/2012; health brochures);

(2) adding a follow-up questionnaire to assess the original Tai Chi group after 3 months post-intervention and the cross-over control group at the end of the Tai Chi instruction; questions on diabetes self-efficacy and depression were removed from the Intake and Post-test Questionnaires to reduce participant burden (Baseline Questionnaire, English + Spanish, version 2, 8/6/2012; Post-test Questionnaire, English + Spanish, version 2, 8/6/2012; Follow-up Questionnaire, English + Spanish, version 1, 8/6/2012);

(3) changing contact information for Rosalba Hernandez, removing Guadalupe Ramirez, and adding Marya Estrella as key research personnel (Appendix P);

(4) although no changes will be made to the number of organizations collaborating with UIC, there will be a change in Creation's Touch's contract since that site will no longer have to provide the physical activity instructor; a updated IRB Authorization Agreement was also submitted for Centro Comunitario Juan Diego (revised Appendix K; IAA signed by Executive Director, 8/3/2012); and

(5) submission of revised recruitment and consent documents reflecting the above; participants in both groups will receive compensation for answering baseline and post-test questionnaires (total $40) but will not receive compensation when answering the follow-up questionnaires; like those participants responding to the 6-week questionnaires, participants will be entered into a raffle and the prizes will be mailed if necessary (Flyer, English + Spanish, version 3, 8/6/2012; CFHC Invitation Letter, English + Spanish, version 2 + version 1, 8/6/2012; Recruitment Script, English + Spanish, version 5, 8/6/2012; Newsletter Blurb Phase 2, English + Spanish, version 3, 8/6/2012; Physician's Letter, version 2, 8/6/2012; Consent document, English + Spanish, version 6, 8/6/2012).

Approved Subject Enrollment #:   70

Performance Sites: UIC, Villa Guadalupe Senior Services, Inc., Chicago Family Health Center, Inc., Creation's Touch, Centro Comunitario Juan Diego

APPENDIX G (continued)

Page 3 of 4

Sponsor: National Institutes of Health
PAF#:   2009-02182
Grant/Contract No: P30AG022849-07
Grant/Contract Title: Roybal Center for Translational Research on Aging-
stress reduction with Tai Chi for elderly Hispanics with diabetes.
Research Protocol(s):
    a) Stress Reduction with Tai Chi in Elderly Hispanics with Diabetes; Version 5; 08/06/2012
Recruiting Material(s):
    a) Flyer (English); Version 3; 08/06/2012
    b) Flyer (Spanish); Version 3; 08/06/2012
    c) CFHC Invitation Letter (English); Version 2; 08/06/2012
    d) CFHC Invitation Letter (Spanish); Version 1; 08/06/2012
    e) Recruitment/Screening Script (English); Version 5; 08/06/2012
    f) Recruitment Script (Spanish); Version 5; 08/06/2012
    g) Newsletter Blurb - Phase 2 (English); Version 3; 08/06/2012
    h) Newsletter Blurb - Phase 2 (Spanish); Version 3; 08/06/2012
    i) Physician's Letter Stress Reduction Study; Version 2; 08/06/2012
Informed Consent(s):
    a) Stress Reduction for Elderly Hispanics Study (English); Version 6; 08/06/2012
    b) Stress Reduction for Elderly Hispanics Study (Spanish); Version 6; 08/06/2012

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
08/09/2012	Amendment	Expedited	08/13/2012	Approved

Please be sure to:

→ **Use only the IRB-approved and stamped consent document(s) and/or HIPAA Authorization form(s) enclosed with this letter when enrolling subjects.**

→ Use your research protocol number (2010-0816) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
"UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB #2 has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

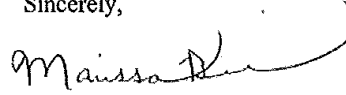**Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.**

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 996-9299. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

APPENDIX G (continued)

Page 4 of 4

Sincerely,

Marissa Benni, M.S.
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects

Enclosure(s):

1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
2. **Informed Consent Document(s):**
   a) Stress Reduction for Elderly Hispanics Study (English); Version 6; 08/06/2012
   b) Stress Reduction for Elderly Hispanics Study (Spanish); Version 6; 08/06/2012
3. **Recruiting Material(s):**
   a) Flyer (English); Version 3; 08/06/2012
   b) Flyer (Spanish); Version 3; 08/06/2012
   c) CFHC Invitation Letter (English); Version 2; 08/06/2012
   d) CFHC Invitation Letter (Spanish); Version 1; 08/06/2012
   e) Recruitment/Screening Script (English); Version 5; 08/06/2012
   f) Recruitment Script (Spanish); Version 5; 08/06/2012
   g) Newsletter Blurb - Phase 2 (English); Version 3; 08/06/2012
   h) Newsletter Blurb - Phase 2 (Spanish); Version 3; 08/06/2012
   i) Physician's Letter Stress Reduction Study; Version 2; 08/06/2012

cc: Laurie Ruggiero, Institute for Health Research and Policy, M/C 275
     Robin J. Mermelstein, Institute for Health Research and Policy, M/C 275

APPENDIX G (continued)

Approval Notice
Amendment to Research Protocol and/or Consent Document – Expedited Review
UIC Amendment # 3

November 16, 2012

Amparo Del Castillo, MD
Institute for Health Research and Policy
1747 W. Roosevelt Road, Room 555
M/C 275
Chicago, IL
Phone: (312) 413-9490 / Fax: (312) 996-3212

RE: **Protocol # 2010-0816**
"Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes"

Dear Dr. Castillo:

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and/or consent form under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

Amendment Approval Date: November 15, 2012
Amendment:
   Summary: UIC Amendment #3 dated October 31, 2012 (received 11/12/2012) is an investigator-initiated amendment regarding the following (1) Removing Creation's Touch as a research site (Initial Review, v5, 10/30/2012; revised Protocol, v6, 10/30/2012; revised Appendix K); (2) Revising the recruitment documents to reflect the change (Physician's Letter, v3, 10/30/2012; CFHC Invitation Letter-Spanish, v2, 10/30/2012; CFHC Invitation Letter-English, v3, 10/30/2012); (3) Revising the consent documents to reflect the change (English Consent, v7, 10/31/2012; Spanish Consent, v7, 10/31/2012); (4) adding Chicago Family Health Center logo to the Invitation Letter.
Approved Subject Enrollment #:   70
Performance Sites: UIC, Villa Guadalupe Senior Services, Inc., Chicago Family Health Center, Inc., Centro Comunitario Juan Diego
Sponsor: National Institutes of Health
PAF#:   2009-02182

APPENDIX G (continued)

2010-0816   Page 2 of 3   November 16, 2012

Grant/Contract No: P30AG022849-07
Grant/Contract Title: Roybal Center for Translational Research on Aging-
stress reduction with Tai Chi for elderly Hispanics with diabetes.
Research Protocol:
    a) Stress Reduction with Tai Chi in Elderly Hispanics with Diabetes; Version 6, 10/30/2012
Recruiting Materials:
    a) Physician's Letter Stress Reduction Study; Version 3, 10/30/2012
    b) CFHC Invitation Letter (Spanish); Version 2, 10/30/2012
    c) CFHC Invitation Letter (English); Version 3, 10/30/2012

Informed Consents:
    a) Stress Reduction for Elderly Hispanics Study (English); Version 7, 10/31/2012
    b) Stress Reduction for Elderly Hispanics Study (Spanish); Version 7, 10/31/2012
Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
11/12/2012	Amendment	Expedited	11/15/2012	Approved

Please be sure to:

→ Use your research protocol number (2010-0816) on any documents or correspondence with the IRB concerning your research protocol.
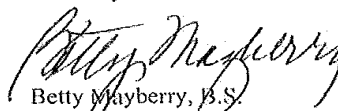
→ Review and comply with all requirements on the enclosure,
"UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB #2 has the right to seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 355-2764. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Betty Mayberry, B.S.
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects

APPENDIX G (continued)

Enclosures:
  1. **UIC Investigator Responsibilities, Protection of Human Research Subjects**
  2. **Data Security Enclosure**
  3. **Informed Consent Documents:**
      a) Stress Reduction for Elderly Hispanics Study (English); Version 7, 10/31/2012
      b) Stress Reduction for Elderly Hispanics Study (Spanish); Version 7, 10/31/2012
  4. **Recruiting Materials:**
      a) Physician's Letter Stress Reduction Study; Version 3, 10/30/2012
      b) CFHC Invitation Letter (Spanish); Version 2, 10/30/2012
      c) CFHC Invitation Letter (English); Version 3, 10/30/2012

cc: Laurie Ruggiero, Faculty Sponsor , M/C 275
       Robin J. Mermelstein, Institute for Health Research and Policy, M/C 275

APPENDIX G (continued)

Approval Notice
Amendment to Research Protocol and/or Consent Document – Expedited Review
UIC Amendment # 4

August 7, 2013

Amparo Castillo, MD
Institute for Health Research and Policy
1747 W. Roosevelt Rd, Rm 555, M/C 275
Chicago, IL
Phone: (312) 413-9490 / Fax: (312) 996-3212

RE: **Protocol # 2010-0816**
       "Stress Reduction with Tai Chi for Elderly Hispanics with Diabetes"

Dear Dr. Castillo:

Members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research and/or consent form under expedited procedures for minor changes to previously approved research allowed by Federal regulations [45 CFR 46.110(b)(2)]. The amendment to your research was determined to be acceptable and may now be implemented.

Please note the following information about your approved amendment:

<u>Amendment Approval Date:</u>   August 5, 2013
<u>Amendment:</u>
    Summary: UIC Amendment #4 dated July 19, 2013, received July 24, 2013 is an investigator-initiated to: 1) add a post-intervention assessment for the control group undergoing the Tai Chi instruction. Revised the protocol-Version 7, July 19, 2012; 2) Revision to the consent forms reflecting the changes in the protocol and procedures-Stress Reduction for Elderly Hispanic Study, version 8, 7/19/13; Stress Reduction for Elderly Hispanics Study (Spanish, version 8, July 19, 2013; 3) Changes in the instruments with the addition of the Post-Questionnaire-2 (English) version 1, 7/19/13; Post-test Questionnaire-2 (Spanish) version 1, 7/19/13; 4) additional of key research personnel: Shikhi Bhansari. His training is current and a revised Appendix P was included. Also, the removal of Mayra Estrella and Maria del Carmen Garcia as key personnel.
<u>Research Protocol(s):</u>
    a) Stress Reduction with Tai Chi in Elderly Hispanics with Diabetes; Version #7 07/19/2013
<u>Informed Consent(s):</u>
    a) Stress Reduction for Elderly Hispanics Study (English); Version #8; 07/19/2013

APPENDIX G (continued)

b) Stress Reduction for Elderly Hispanics Study (Spanish); Version #8; 07/19/2013

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
07/24/2013	Amendment	Expedited	08/05/2013	Approved

Please be sure to:
→ **Use only the IRB-approved and stamped consent document(s) and/or HIPAA Authorization form(s) enclosed with this letter when enrolling subjects.**

→ Use your research protocol number (2010-0816) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure,
    "UIC Investigator Responsibilities, Protection of Human Research Subjects"
        (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB #2 has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 355-2939. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Jewell Hamilton, MSW
IRB Coordinator, IRB # 2
Office for the Protection of Research Subjects

Enclosure(s):

1. **Informed Consent Document(s):**
    a) Stress Reduction for Elderly Hispanics Study (English); Version #8; 07/19/2013
    b) Stress Reduction for Elderly Hispanics Study (Spanish); Version #8; 07/19/2013

cc: Laurie Ruggiero, Faculty Sponsor, Institute for Health Research and Policy, M/C 275
        Robin J. Mermelstein, Institute for Health Research and Policy, M/C 275

APPENDIX H

Table V-A. Baseline Characteristics of Immigrants in Cohort 1: Tai Chi and Control Groups			
Variable	**Tai Chi**	**Control**	*P* **value**
	N= 16	N= 14	
Age, **years, mean (SD)**	61.6 (8.6)	61.1 (4.5)	0.85
Sex			
Female, **n(%)**	11 (36.7)	7 (23.3)	0.29
Male, **n(%)**	5 (16.67)	7 (23.3)	
Weight, **kg, mean (SD)**	186.0 (39.7)	196.0 (27.1)	0.42
BMI, **kg/m², mean (SD))**	34.7 (5.4)	33.93 (6.8)	0.72
A1C, %, **mean (SD)**	7.74 (1.27)	8.45 (1.9)	0.23
Blood pressure			
Systolic, **mm Hg, mean (SD)**	130.5(21.3)	133.1(19.6)	0.73
Diastolic, **mmHg, mean (SD)**	73.8(10.1)	73.6 (7.0)	0.93
Years diagnosed with T2D, **years, mean (SD)**	7.1 (6.7)	10.0 (8.3)	0.3
Years of education, **years, mean (SD)**	9.75 (4.5)	7.35 (3.5)	0.12
Marital Status ***			
Married, **n(%)**	12 (40.0)	8 (26.67)	0.75
Single/Divorced/Separated/Widowed, **n(%)**	4 (13.33)	6 (20.0)	
Years living in the US, **years, mean (SD)**	26.9 (18.3)	30.4(9.3)	0.54
Language ***			
English, **n(%)**	1 (3.3)	0 (0.0)	1.0
Spanish, **n(%)**	15 (53.3)	14 (46.7)	
Insurance ***			
Yes, **n(%)**	12 (40.0)	6 (20.0)	0.083 **
No/Don't know, **n(%)**	4 (13.3)	8 (26.7)	
Employment ***			
Employed for wages/Self-employed, **n(%)**	2 (6.67)	4 (13.3)	0.79
Unemployed/Unable to work, **n(%)**	5 (16.67)	3 (10.0)	
Homemaker, **n(%)**	4 (13.3)	2 (6.67)	
Retired, **n(%)**	5 (16.67)	5 (16.67)	
Household Income ***			
≤ 24,999 per year, **n(%)**	10 (41.67)	9 (37.5)	0.27
≥ 25,000, **n(%)**	2 (8.33)	0 (0)	
Don't know/Not reported, **n(%)**	1 (4.17)	2 (8.33)	
Medication use ***			
Pills, **n(%)**	12 (41.38)	3 (10.34)	0.0465*
Insulin alone or in combination, **n(%)**	3 (10.34)	6 (20.69)	
None/Not reported, **n(%)**	1 (3.45)	4 (13.79)	

*Denotes significance at p =0.05 level

** Denotes trend toward significance

*** Using Fisher's Exact test since 50% of cells have expected counts less than 5

APPENDIX I

Table V-B. Baseline Characteristics of Randomized Controlled Pilot: Tai Chi and Control Groups-Intent to Treat			
Variable	Tai Chi	Control	*P* value
	N= 20	N= 20	
Age, years, mean (SD)	62.4 (9.1)	60.9 (6.6)	0.54
Sex			
Female, n(%)	13 (65)	11 (55)	0.52
Male, n(%)	7 (35)	9 (45)	
Weight, kg, mean (SD)	189.3 (38.5)	199.2 (38.7)	0.42
BMI, kg/m^2, mean (SD)	34.9 (5.9)	34.7 (7.6)	0.95
A1C, %, mean (SD)	7.56 (1.2)	8.36 (1.6)	0.09
Blood pressure			
Systolic, mm Hg, mean (SD)	131.8(23.0)	131.1(18.1)	0.92
Diastolic, mmHg, mean (SD)	73.6(9.9)	74.0 (7.8)	0.91
Years diagnosed with T2D, years, mean (SD)	9.2 (10.1)	10.7 (8.3)	0.59
Years of education, years, mean (SD)	10.4 (5.1)	9.4 (4.8)	0.51
Marital Status			
Married, n(%)	14 (70)	13(65)	0.74
Single/Divorced/Separated/Widowed, n(%)	6 (30)	7 (35)	
Place of birth			1.00***
US, n(%)	4 (20)	5 (25)	
Mexico/Other, n(%)	16 (80)	15 (75)	
Years living in the US, years, mean (SD)	35.1 (23.4)	36.6(18.1)	0.83
Language			1.00***
English, n(%)	5 (25)	4 (20)	
Spanish, n(%)	15 (75)	16 (80)	
Insurance			
Yes, n(%)	16 (80)	11 (55)	0.09
No/Don't know, n(%)	4 (20)	9 (45)	
Employment			
Employed for wages/Self-employed, n(%)	4 (20)	7 (35)	0.69
Unemployed/Unable to work, n(%)	5 (25)	3 (15)	
Homemaker, n(%)	4 (20)	3 (15)	
Retired, n(%)	7 (35)	7 (35)	
Household Income			
≤ 24,999 per year, n(%)	11 (55)	10 (50)	0.94
≥ 25,000, n(%)	6 (30)	7 (35)	
Don't know/Not reported, n(%)	3 (15)	3 (15)	
Diabetes Distress, mean (SD)	2.3 (1.4)	1.7 (1.5)	0.20
Perceived Stress, mean (SD)	17.5 (8.8)	14.1 (6.4)	0.18
Functional Social Support, mean (SD)	2.2 (1.5)	2.4 (1.8)	0.80
Medication use			
Pills, n(%)	14 (70)	9 (45)	0.25
Insulin alone or in combination, n(%)	4 (20)	6 (30)	
None/Not reported, n(%)	2 (10)	5 (25)	

*Denotes significance at p =0.05 level   ** Denotes trend toward significance
*** Using Fisher's Exact test since 50% of cells have expected counts less than 5.

APPENDIX J

Table VIII-A. Pre-Post-test Changes of All Tai Chi Participants – Intent to Treat					
Outcome Measures	**N**	**Mean (SD)**		**Change (95% CI)**	**P value**
		Baseline	**12-week**	**Within-Group Change**	
Primary Outcome					
A1C, %	41	7.79 (1.19)	7.58 (1.14)	-0.21 (-0.38 to -0.04)	0.0176*
Secondary Outcomes					
Systolic Blood Pressure, mm Hg	41	129.22 (21.03)	130.07 (21.39)	0.84 (-3.68 to 5.37)	0.71
Diastolic Blood Pressure, mm Hg	41	72.19 (9.30)	73.65	1.46 (-2.15 to 5.08)	0.42
Diabetes Distress	41	2.02 (1.43)	1.66 (1.36)	-0.35 (-0.70 to -0.01)	0.0464*
Perceived Stress	41	15.07 (7.54)	14.59 (7.64)	-0.49 (-2.05 to 1.07)	0.53
Immigration-related Stress	29	2.05 (0.92)	1.77 (0.64)	-0.29 (-0.49 to -0.09)	0.0061*

*Denotes significance at p =0.05 level

VITA

Amparo Castillo, MD, PhD
(773) 616-0417
amparo@uic.edu
amparo07@gmail.com

CURRICULUM VITAE - 2016

PERSONAL STATEMENT

My work seeks to address health disparities and enhance the well-being and quality of life of ethnic minorities by introducing innovative behavioral and health education programs, and by developing educational trainings and curricula for community health workers.

EDUCATION

Doctor of Philosophy	Public Health: Community Health Sciences School of Public Health University of Illinois at Chicago Chicago, IL	2016
Master of Science	Physiology Maharishi University of Management Fairfield, IA	1994
Doctor of Medicine	Medicine and Surgery Javeriana University School of Medicine & Surgery Bogota, Colombia (South America)	1982

EMPLOYMENT

Director of Research and Training - Senior Trainer	Midwest Latino Health Research Training and Policy Center Jane Addams College of Social Work University of Illinois at Chicago Chicago, IL	2004 - present
Co-Director	Recruitment, Retention and Community Engagement Core-Center for Clinical and Translational Sciences (CCTS) University of Illinois at Chicago Chicago, IL	2014 - present
Principal Investigator	Midwest Latino Health Research Training and Policy Center Jane Addams College of Social Work University of Illinois at Chicago Chicago, IL	2012 – 2014
Instructor	Introduction to Qualitative Research Methods in Public Health-Community Health Sciences- School of Public Health- University of Illinois at Chicago Chicago, IL	2012-
Principal Investigator	Midwest Roybal Center for Health Promotion and Translation Institute for Health Research and Policy University of Illinois at Chicago Chicago, IL	2009 - 2014
Senior Research Associate	Institute for Health Research and Policy School of Public Health University of Illinois at Chicago Chicago, IL	2009 - 2012

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Project Director	Midwest Latino Health Research Training and Policy Center Jane Addams College of Social Work University of Illinois at Chicago Chicago, IL	2004 - 2007
Coordinator of Training and Research	Midwest Latino Health Research Training and Policy Center Jane Addams College of Social Work University of Illinois at Chicago Chicago, IL	2003 - 2004
Assistant Professor of Physiology and Research Faculty	College of Maharishi Vedic Medicine and Center for Natural Medicine and Prevention Maharishi University of Management Fairfield, IA	1998 - 2003
Research Faculty	Center for Health and Aging Studies Maharishi University of Management Fairfield, IA	1995 - 1998

HONORS AND AWARDS

Junior Faculty Fellow – Redes en Acción Cancer Program Midwest Latino Health Research Training and Policy Center University of Illinois at Chicago Chicago, IL	2003
International Assistantship and International Revolving Scholarship to pursue a MS in Physiology Maharishi International University, Fairfield, IA	1991-1994

RESEARCH

Funding Source	Grant Title	Role in Project	Amount	Years
Healthcare Foundation of Northern Lake County	Diabetes Control for Latinos in Lake County	Principal Investigator	$100, 000	2012-2014
National Institutes of Health (NIH)- National Institute on Aging: Midwest Roybal Center for Health Promotion	Stress Reduction with Tai Chi for Hispanic Elderly with Diabetes	Principal Investigator	$39, 000	2009-2013
NIH–National Heart, Lung and Blood Institute (NHLBI): Academic Research Enhancement Award (AREA) # 1 R15 HL60242-01	Stress Reduction and Myocardial Ischemia in Blacks	Principal Investigator	$90, 000	1998-2003
NIH-NHLBI: Minority Supplement Award # HL51519-S2	Stress Reduction and Carotid Atherosclerosis in Hypertensive African Americans	Principal Investigator	$100, 000	1995-1998

CURRICULUM DEVELOPMENT

Diabetes Empowerment Education Program (DEEP)	Co-Author and Senior Trainer
Diabetes Empowerment and Prevention Program (DEPP)	Co-Author and Senior Trainer
Health Education and Lifestyle Program (HELP)	Co-Author and Senior Trainer

PUBLICATIONS

1. Bate-Ambrus, VM, **Castillo, A**., Martinez, E., Campbell, J., Boughton-Price, L., Gutierrez Kapheim, M., Arrom, J., Hernandez, W., Waddy, J., Castillo, S., Schaps, M., Williams, Y.(2015). Many Ingredients, One Sublime Dish: The Recipe for the Passage of Illinois HB5412 into Law. Journal of Ambulatory Care Management, Vol. 38 (3):236–243.
2. Ruggiero L, Riley BB, Hernandez R, Quinn LT, Gerber BS, **Castillo A**, Day J, Ingram D, Wang Y, Butler P. Medical Assistant Coaching to Support Diabetes Self-Care Among Low-Income Racial/Ethnic Minority Populations:

Randomized Controlled Trial. Western Journal of Nursing Research. Feb 25, 2014. DOI: 10.1177/0193945914522862. URL: http://wjn.sagepub.com/content/early/2014/02/25/0193945914522862

3. Gerber B, Rapacki L, **Castillo A**, Tilton J, Touchette D, Mihailescu D, Berbaum M, Sharp L. Design of a trial to evaluate the impact of clinical pharmacists and community health promoters working with African-Americans and Latinos with Diabetes.   BMC   Public   Health.   2012,   12:891.   DOI: 10.1186/1471-2458-12-891.   URL: http://www.biomedcentral.com/1471-2458/12/891

4. Ruggiero, L, **Castillo, A**, Quinn, L, Hochwert, M. Translation of the Diabetes Prevention Program's Lifestyle Intervention: Role of Community Health Workers. Current Diabetes Reports. Published online: February 21, 2012.

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10. Schneider RH, **Castillo-Richmond A,** Alexander CN, Myers H, Kaushik V, Norris K, Cook R, Haney C, Rainforth M. "Rationale and Design of a Randomized Controlled Trial of Stress Reduction for Hypertensive Cardiovascular Disease in African Americans"; Behavioral Medicine. 27(2):83-95. 2001

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14. **Castillo A.** "Brote de Hepatitis en Murrí, Antioquia"; Boletín Epidemiológico de Antioquia. Servicio Seccional de Salud de Antioquia, Medellín, Colombia. June, 1982

PRESENTATIONS

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1. Castillo, A., Ramirez, L., Gutierrez, D. Partnership between academia and community to improve diabetes outcomes among Latino immigrants in Lake County, IL. Poster presented at the American Public Health Association Conference, New Orleans, LA. November 18th, 2014.

2. Castillo A., Aponte-Soto L., Hernandez R., Ruggiero L. Tai Chi for stress reduction and glycemic control among Hispanic older adults. Poster presented at the American Public Health Association Conference, Boston, MA. November 4th, 2013.

3. Kieso, T., Castillo, A. Patient Centered Care Collaboration (*PCCC*) in Chicago: The Health Empowerment and Lifestyle Program (*HELP*) for African Americans with Obesity, Hypertension and/or Diabetes. Oral presentation at the American Public Health Association Conference, Boston, MA. November 4th, 2013.

4. Boughton L., Castillo A., Bate-Ambrus V. The Journey to Certification of Community Health Workers in Illinois. Oral presentation at the American Public Health Association Conference, Boston, MA. November 5th, 2013.

5. Castillo A, Aponte-Soto L, Hernandez R. Assessing stress and stress reduction with Tai Chi among elderly Hispanics with diabetes. Poster presented at the American Public Health Association Conference, Washington, DC. October 30 - November 2nd, 2011.

6. Castillo, A. Implementing the Diabetes Empowerment Education Program. Invited presentation at the Third Annual Health Disparities Conference: 'Building Partnerships to Eliminate Health Disparities' sponsored by Xavier University of Louisiana, New Orleans, LA. April 19-21, 2009.

7. Castillo, A., Giachello, A. The Center of Excellence in the Elimination of Disparities: CEED @ Chicago. Invited presentation on the REACH Experience at the 20th National Conference on Chronic Disease Prevention and Control: Cultivating Healthy Communities. National Harbor, Maryland, February 23-25, 2009.

8. Castillo, A. The Chicago Southeast Diabetes Community Action Coalition. Invited presentation at the "The Domino Effect: Social Determinants of Health" of the National Health Action Conference of Families USA. Washington, DC., January 29-31, 2009.

9. Castillo, A. Reducing Health Disparities Faster: Addressing Social Determinants of Health. Presentation to the Congressional Hispanic/Latino Caucus as part of the Disparity Reducing Advances Project (DRA) Foresight Briefing, in Washington, D.C. December 6th, 2007.

10. Castillo, A, Giachello, A., Bates, R., Arrom, J., Sanchez, C. Empowerment and Adult Education in a Community Intervention for Hispanic/Latinos with Diabetes, invited presentation at the National Hispanic Medical Association Conference, San Antonio, TX. March 22-25, 2007.

11. Castillo, A, Giachello, A., Arrom, J., Bates, R., Hsieh, C.M., Sanchez, C. Use of Empowerment Theory and Adult Education in Affecting Clinical and Behavioral Outcomes in Patients with Diabetes. Poster presented at the American Public Health Association Conference. Boston, MA., November 6, 2006.

12. Castillo, A., Giachello, A., Ramirez, D. Strategies for Altering Dietary Practices in the Community : Up Close and Personal with Fattening Foods. Invited workshop at Using Research for Understanding and Action- Workshop on Latino Obesity by Inter-University Program for Latino Research at University of Notre Dame, IN. July 24-26th, 2006.

13. Castillo, A, Londono, M., Giachello, A., Sanchez, C. A Participatory Training Program for Community Diabetes Educators. Poster presented at the CDC Diabetes and Obesity Conference. Denver, CO., May 15-17, 2006.

14. Castillo, A.., Giachello, A., Arrom, J., Sanchez, C. Effectiveness of an Educational Diabetes Curriculum : Preliminary Findings. Presented at the National Leadership Summit on Eliminating Racial and Ethnic Disparities in Health – The Office of Minority Health. Washington, DC., January 9-11, 2006.

15. Castillo-Richmond, A. Complementary and Alternative Medicine Modalities in the Prevention and Treatment of Cardiovascular Disease. Presented at the Bi-National US-Mexico Health Conference- Chicago, IL, October 11-12, 2005.

16. Castillo-Richmond, A.. Medicina Complementaria y Alternativa para la Prevencion y el Tratamiento de Enfermedades Cardiovasculares. Presented at the Midwest Latino Health Research Training and Policy Center 10th. Year Conference, "Connecting to Our Past and Building Our Future", Chicago. June 6, 2003.

17. Castillo-Richmond, A. Complementary and Alternative Medicine Modalities in the Prevention and Treatment of Cardiovascular Disease. Presented at the CDC's 17th. National Conference on Chronic Disease Prevention and Control, "Gateway to Lifelong Health—The Community Connection". Saint Louis, MO. February 21st, 2003.

18. Castillo-Richmond, A., Schneider, R.H., Alexander, C.N., Cook, R., Myers, H., Haney, C., Rainforth, M.; Effects of the Transcendental Meditation Program on carotid atherosclerosis; Presented at the Thirteenth International Interdisciplinary Conference on Hypertension in Blacks, Charleston, South Carolina, July 14, 1998.

19. Castillo-Richmond, A., Schneider, R.H., Alexander, C.N., Cook, R., Myers, H., Haney, C., Effects of stress reduction on carotid artery atherosclerosis and compliance in hypertensive African Americans. Presented at the Third Annual National Heart, Lung and Blood Institute Cardiovascular Minority Research Supplement Awardee Session, at the 68th. Scientific Sessions of the American Heart Association, Anaheim, CA, November 12, 1995.

Trainings: Led more than 50 training sessions as Trainer for the Diabetes Empowerment Education Program (DEEP)

OTHER AFFILIATIONS

American Association of Diabetes Educators (AADE), Member	2013 - present
American Public Health Association (APHA), Member	2011- present
American Diabetes Association (ADA) - National Sub-Committee on Latino Community Initiatives, Member	2011- 2014
	1999 – 2003
American Heart Association, Council on Behavioral Science, Epidemiology and Prevention, Member	2014 – present
	2013 - present
Progress in Community Health Partnerships: Research Education and Action, Reviewer	2012 - present
Health Education Research, Reviewer	2011 - present
Journal of Immigrant and Minority Health, Reviewer	2000 – 2003
Health Promotion and Practice, Reviewer	
Stroke Journal, Reviewer	

REFERENCES

Upon request.