DEVELOPMENT AND EVALUATION OF A CULTURALLY SENSITIVE DIABETES PREVENTION AND MANAGEMENT INTERVENTION IN ELDERLY HISPANICS

A Thesis

Presented to the

Faculty of

California State Polytechnic University, Pomona

In Partial Fulfillment

Of the Requirements for the Degree

Master of Science

In

Agriculture

By

Nicole S. Hummel, RD

2015
SIGNATURE PAGE

THESIS: DEVELOPMENT AND EVALUATION OF A CULTURALLY SENSITIVE DIABETES PREVENTION AND MANAGEMENT INTERVENTION IN ELDERLY HISPANICS

AUTHOR: Nicole S. Hummel, RD

DATE SUBMITTED: Spring 2015

College of Agriculture

Dr. Lisa Kessler, RD
Thesis Committee Chair
Human Nutrition and Food Science

Dr. Bonny Burns-Whitmore, RD
Human Nutrition and Food Science

Ms. Aleida Gordon, RD
Human Nutrition and Food Science
ACKNOWLEDGEMENTS

First, I would like to thank my parents who have provided me with unconditional love and support throughout my life. In addition, I would like to thank my sister Natascha and partner Tim who helped me through all the tough times on this very long journey.

Second, I would like to thank my professors’ Dr. Lisa Kessler and Dr. Bonny Burns-Whitmore who provided me with continued support despite the numerous challenges I faced along the path to completing my thesis. I couldn’t have made it to this point without your educational knowledge and guidance. Thank you for your patience and support! In addition, I would like to thank Ms. Aledia Gordon for joining our committee despite such short notice. Thank you very much for your help.

Next, I would like to thank Dr. Thomas Spalding who went above and beyond the expectations of professor duties. You will forever be remembered and greatly missed.
ABSTRACT

Elderly Hispanic individuals with prediabetes are at high risk for developing type 2 diabetes. The Diabetes Prevention Program (DPP) clinical efficacy trial demonstrated that weight loss can prevent or slow the progression of type 2 diabetes in high-risk populations regardless of ethnicity, age, or gender. Currently, no DPP translation studies have targeted elderly Hispanic populations to determine the feasibility of a community-based DPP intervention. Therefore, it is unknown whether the implementation of a group-based DPP adapted lifestyle intervention in an elderly Hispanic population would decrease risk factors associated with type 2 diabetes. We investigated whether a culturally sensitive diabetes prevention and management intervention derived from the Social Cognitive Theory resulted in changes in body weight, percent body fat, fasting capillary blood glucose, and self-reported physical activity in elderly Hispanics who were either overweight, prediabetic or type 2 diabetic. We hypothesized that weight loss would improve fasting blood glucose levels over time. A total of 15 participants attended an 8-week (1x week) and 4-week non-intervention weight loss intervention adapted from the diabetes prevention program (DPP) curriculum. The outcome variables were measured at week 0 (baseline), 4, 8, and 12 weeks and re-measured at 16 weeks after a 4-week non-intervention period. There were significant reductions in weight (p<.002) and BMI (p<.001) at 12-weeks compared with baseline. Percent body fat did not decrease significantly compared with baseline. Capillary fasting blood glucose levels were not assessed due to lack of data. This study demonstrated that a short-term culturally sensitive diabetes intervention derived from SCT can help elderly Hispanics achieve modest weight loss. Longer interventions are needed to achieve clinically significant
weight loss of 5% and to sustain participant motivation. Due to physical limitations, some elderly individuals may not be able to achieve moderate intensity physical activity levels recommended for clinically significant weight loss.
# TABLE OF CONTENTS

Signature Page ........................................................................................................... ii  
Acknowledgements.................................................................................................. iii  
Abstract ....................................................................................................................... iv  
List of Tables ............................................................................................................. x  
List of Figures ............................................................................................................ xi  

## Chapter I: Introduction .......................................................................................... 1  
  Statement of the Problem .......................................................................................... 6  
  Definition of Terms ..................................................................................................... 6  

## Chapter II: Literature Review ............................................................................... 8  
  Overview of Type 1 and Type 2 Diabetes Mellitus ...................................................... 9  
  Overview of Prediabetes ............................................................................................. 9  
  Diabetes Prevention Clinical Efficacy Trials ............................................................... 12  
  The Diabetes Prevention Program (DPP) Progress ..................................................... 20  
  What is Translational Research? ............................................................................... 23  
  Barriers to Translational Research ........................................................................... 30  

## The Diabetes Prevention Program (DPP) T2 Research Studies ...................... 38  
  DPP T2 Research Conducted in Clinical Settings ...................................................... 39  
  DPP T2 Research in Clinical Settings Using Paraprofessionals ......................... 43  
  DPP T2 Research through the Use of Internet Technology ....................................... 45  
  DPP T2 Research Targeting Minority Groups in Clinical Settings ..................... 47  
  DPP T2 Research Conducted in Community Settings ............................................. 49
Qualitative Assessment ........................................................................................................ 94
  Purpose ............................................................................................................................ 94
  Participant Recruitment .................................................................................................. 94
  Focus Group Study Design .............................................................................................. 95
  Data Analysis .................................................................................................................. 96

Chapter IV: Research Findings .......................................................................................... 98
  Participants ......................................................................................................................... 98
  Informal Cost Evaluation ................................................................................................. 103
  Qualitative Assessment Results ....................................................................................... 104
    Consistent & Non-Consistent Attenders ........................................................................ 104
    Consistent Attenders ..................................................................................................... 105
    Non-Consistent Attenders .............................................................................................. 111

Chapter V: Conclusion ....................................................................................................... 113
  Feasibility of the Diabetes Prevention Program (DPP) T2 Research Study ....... 113
    Qualitative Assessment ............................................................................................... 113
    Demographics ............................................................................................................... 114
    Older Adult/Elderly Participants .................................................................................. 115
    Setting ............................................................................................................................ 116
    Facilitator Delivery Modes ............................................................................................ 118
    Cost Effectiveness ......................................................................................................... 119
  Study Limitations ............................................................................................................ 120
  Study Design & Participants ........................................................................................... 120
  Efficacy ............................................................................................................................ 120
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose &amp; Duration</td>
<td>121</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>124</td>
</tr>
<tr>
<td>Recruitment &amp; Screening</td>
<td>127</td>
</tr>
<tr>
<td>Safety &amp; Adverse Events</td>
<td>127</td>
</tr>
<tr>
<td>Program Adherence through Self-Monitoring</td>
<td>129</td>
</tr>
<tr>
<td>Physical Activity &amp; Weight Loss</td>
<td>130</td>
</tr>
<tr>
<td>Attendance</td>
<td>132</td>
</tr>
<tr>
<td>Summary</td>
<td>133</td>
</tr>
<tr>
<td>References</td>
<td>134</td>
</tr>
</tbody>
</table>
LIST OF TABLES

Table 1  Diabetes Prevention Program Components and Study Design………  21
Table 2  Definition of Terms Pertaining to T1 and T2 Translation Research .......  30
Table 3  DPP T2 Studies Targeting Hispanic or Latino Groups in Community Settings.................................................................................................................. 54
Table 4  Adapted Diabetes Prevention Program Curriculum………… …………..  65
Table 5  Participant Blood Sugar Goals .......................................................... 66
Table 6  Components Included in the Lesson Plan Development ...................... 68
Table 7  DPP Intervention Fat and Calorie Goals………… ………… …………..  70
Table 8  Calorie Amounts and Number of Recommended Servings Sizes in Each Food Group .................................................................................................................. 76
Table 9  Focus Group Interviewing Questions ................................................ 97
Table 10 Baseline Participant Characteristics................................................. 100
Table 11 Modified DPP Sessions & Attendance Rates for TELACU Manor & Casa Participants................................................................................................................. 101
Table 12 Mean (SD) Baseline Descriptive Statistics for Anthropometric Study Measures .................................................................................................................. 102

Figure 13 Changes in Body Weight, Body Mass Index, Percent Body Fat and Fasting Glucose from Baseline to 12-weeks (n=12)................................. 103

Figure 14 Total Percent Weight Loss or Gain for Each Participant at 12 Weeks .... 103
LIST OF FIGURES

Figure 1  NIH clinical and translational science award research model .................... 27
Figure 2  Create your plate ...................................................................................... 77
CHAPTER I

INTRODUCTION

Diabetes is the fourth leading cause of death in the Hispanic population aged 65 years or older (Gorina et al., 2006). Type 2 diabetes accounts for 90-95% of all reported cases and is associated with obesity and sedentary lifestyle (Raymond & Stump, 2008). Type 2 diabetes is a metabolic disorder characterized by insulin resistance. Insulin resistance occurs from either a decreased insulin response to blood glucose or poor insulin sensitivity at the peripheral tissue level (American Diabetes Association, 2013). Impaired insulin production or sensitivity can cause hyperglycemia (elevated blood glucose), which is associated with microvascular and macrovascular diseases such as kidney disease (nephropathy), eye disease (retinopathy), nervous system damage (neuropathy), peripheral vascular disease, heart disease, stroke, and many other conditions (Mckinlay & Marceau, 2000). Health care costs to treat diabetes and its associated complications reached $245 billion in direct and indirect medical expenditures in 2012. This is a 41 percent increase since 2007 and is largely attributed to hospital inpatient care (direct costs) and lost work productivity (indirect costs) (Yang et al., 2013).

Certain racial/ethnic groups consistently experience higher rates of diabetes compared to whites (National Diabetes Statistics Report, 2014). The prevalence of diabetes among various ethnic groups is:

- 7.6% of non-Hispanic whites
- 9.0% of Asian Americans
- 12.8% of Hispanics
• 13.2% of non-Hispanic blacks
• 15.9% of American Indians/Alaskan Natives

The nutritional health of Hispanics is of particular importance because Hispanics are the fastest growing minority group in the U.S. According to the U.S. Census Bureau, the Hispanic population in 2013 was over 54 million, comprising more 17% of the U.S. total population (U.S. Census Bureau, 2014). By the year 2060, the Hispanic population is expected to increase to 128.8 million, representing 31% of the U.S. population (U.S. Census Bureau, 2014). In Los Angeles County, the Hispanic population reached 4.8 million in 2013, which is the largest urban Hispanic population in the United States (U.S. Census Bureau, 2014). The elderly Hispanic population aged 65 years and older is expected to contribute largely to the increase in population. For example, by 2050, the elderly Hispanics population is expected to grow by 17 million, and by 2019, Hispanics projected to be the largest racial/ethnic minority group in this age category (U.S. Department of Health and Human Services Administration for Community Living, 2010).

Along with the rise in the aging minority population, the prevalence of type 2 diabetes is expected to dramatically increase in individuals at high risk for diabetes (Centers of Disease Control and Prevention, 2010).

One of the goals of the Healthy People 2020 is to decrease health disparities. Health disparities are preventable differences in the burden of disease or opportunities to achieve optimal health experienced by socially disadvantaged populations (Fielding, 2009). The Hispanic population is currently suffering from a variety of health and nutrition disparities. A recent study indicated that Mexican-Americans are two times more likely to have diabetes than non-Hispanic whites (Cowie et al., 2009). In addition,
Hispanics have higher rates of diabetes related end-stage renal disease and have a 50% greater chance of experiencing a diabetes related death compared to non-Hispanic whites (U.S. Department of Health and Human Services, 2013). The most recent data from the Healthy People 2010 final review indicated that health disparities exist in two key areas 1) new cases of diabetes and 2) prevalence of diabetes, which are 10-49% and 50-99% higher among Hispanics compared to white non-Hispanics (Healthy People 2010, 2010). This review indicates that we have moved away from the Healthy People 2010 target goal of 3.8 cases per 1000 persons to 8.0 cases per 1000 persons, suggesting that health disparities continue to persist in the U.S.

Reducing health disparities within the Hispanic population requires cultural competency. An understanding of cultural factors that shape lifestyle and dietary habits associated with risk of diabetes is important to facilitate positive health outcomes (American Dietetic Association, 2010). There are numerous multifactorial barriers that contribute to the prevalence of type 2 diabetes in the Hispanic population. Studies have shown that changes in lifestyle, such as poor diet and decreased physical activity levels contribute to the increased risk of type 2 diabetes within the U.S. Hispanic population (Hunt et al., 2003). Obesity, which is a significant risk factor for diabetes (Stern et al., 1998) is significantly higher in Hispanics compared to non-Hispanic whites (Ogden et al., 2006). In addition, there is evidence indicating that social pressures and cultural influences have shaped specific health beliefs regarding the development and treatment of diabetes. For example, Hispanics are more prone to believe an emotional event may trigger the onset of diabetes (Loewe et al., 2000; Adams et al., 2003) and may also follow a folklore health model in combination with a biomedical health model (Jezewski et al.,
2002). Furthermore, Hispanic women are more likely to adopt ‘obesity-tolerant’ attitudes and display less dissatisfaction with their body weight (Rand et al., 1990; Kimanyika et al., 1993) compared to non-Hispanic whites. Inadequate health care and lack of culturally sensitive information due to communication barriers are also environmental factors that hinder appropriate diabetes related care among Hispanics (Agency for Healthcare Research and Quality, 2013; Reimann, Talavera, & Salmon, 2004).

Preventing and managing diabetes is an important public health opportunity to decrease health disparities among high-risk populations. Numerous large randomized controlled trials conducted in diverse countries have demonstrated that intensive lifestyle interventions, which focus on improving dietary and physical activity behaviors, are effective in preventing or delaying the onset of type 2 diabetes. (Pan et al., 1997; Toumillehto et al., 2001; Knowler et al., 2002). These studies have shown that a modest weight loss of 5% to 10% reduced the incidence of diabetes by 41% to 58% in overweight individuals with prediabetes. The U.S. based Diabetes Prevention Program (DPP) efficacy trial, showed that the risk of type 2 diabetes significantly decreased in all groups regardless of ethnicity, age or gender, and demonstrated that the potential for reducing health disparities in high-risk populations is possible with achieving clinically significant weight loss (Knowler et al., 2002).

The Diabetes Prevention Program (DPP) provided the foundation for conducting type 2 translation (T2) research. Upon completion of the DPP clinical trial, the lifestyle intervention protocol and curriculum was made available online allowing for the intervention to be tested in real world settings. Since the completion of DPP, numerous T2 studies have implemented the intervention into a variety of clinical and community
settings (West et al., 2011; Ackermann et al., 2008). Type 2 translation research (T2) is needed to examine how to effectively implement and disseminate evidence-based research into real-world settings under less ideal conditions (Brownson et al., 2012). (http://www.cdc.gov/diabetes/prevention/recognition/curriculum.htm). The majority of DPP T2 research studies have shown to produce short-term clinically significant weight loss (Whittemore, 2011). However, it is uncertain whether or not these interventions are able to produce sustainable weight loss and prevent diabetes long-term. While clinical efficacy trials show promise in reducing incidences of diabetes, these study protocols may not reflect standard health care practices where resources and time are limited. DPP T2 research can help identify alternative implementation methods and strategies that result in sustainable behavior change, such as long-term weight loss.

One of the main goals of T2 research is to target populations that can benefit from new evidence based knowledge gained in clinical efficacy trials and test new implementation strategies that are effective for high risk groups. (Woolf, 2008). However, research discoveries do not always reach populations suffering from health disparities (Fleming et al., 2008). For example, DPP translation studies targeting minority populations, particularly Hispanics groups, are limited, and recruitment samples tend to be overrepresented by Caucasian, middle age females. (Venditti & Kramer, 2012). In addition, diabetes prevention efforts have not widely targeted elderly individuals at risk for type 2 diabetes. However, it is estimated that, “40 percent of U.S. Hispanic or Latino adults ages 40 to 74 currently have prediabetes.” (National Institutes of Health, 2004), which is likely to significantly increase over the next decade. Considering that 10% of individuals with prediabetes progress to diabetes annually and 70% eventually develop
type 2 diabetes (Tuomilehto et al., 2001; Knowler et al., 2002), diabetes prevention efforts are also needed in elderly populations where the window of opportunity to prevent diabetes is greatly reduced.

Providing culturally sensitive interventions based on behavioral strategies are important components to effectively translating evidence based research into real world settings. Evidence suggests that incorporating culturally appropriate constructs e.g. effective communication into diabetes education results in an increase in patient satisfaction (Beach, 2005). Therefore, the importance of understanding how cultural attitudes, beliefs, and values relate to diabetes health care practices at the provider level is critical in the prevention and management of type 2 diabetes (Reimann et al., 2004). In addition, integrating behavioral frameworks that aid in inducing behavior change are also important constructs to include in diabetes interventions. Bandura’s social cognitive theory, which emphasizes self-efficacy, has shown to be the most effective behavioral model in type 2 diabetes self-management outcomes (Krichbaum, Aarestad, & Buethe, 2003) and the association between high-self efficacy and exercise behavior have also been observed (Delahanty, Williamson, Meigs, Nathan, & Hayden). Self-efficacy refers to how confident one is in their ability to control their own health outcomes (Bandura, 2004). As the incidence and prevalence of diabetes continues to rise in the U.S., the implementation and dissemination of culturally sensitive and behavioral based interventions are needed in populations suffering from health disparities.

The purpose of this study was to develop and evaluate a culturally sensitive diabetes prevention and management intervention aimed at elderly Hispanics. The curriculum was adapted from the Diabetes Prevention Program (DPP) and derived from
Social Cognitive Theory. The primary goal of this study was to determine if a modified less intensive version of the DPP intervention resulted in clinically significant reductions in body weight (5% of original weight), percent body fat, fasting plasma blood glucose, and self-report physical activity in elderly Hispanics with prediabetes and type 2 diabetes.

**Statement of the Problem**

Currently, there are no DPP T2 research studies that have targeted elderly Hispanic populations and therefore it is unknown whether a culturally sensitive behavioral based lifestyle intervention is feasible in this high risk population.

**Definition of Terms**

**Type 2 diabetes:** A metabolic disorder characterized by insulin resistance. Insulin resistance occurs from either a decreased insulin response to blood glucose or poor insulin sensitivity at the peripheral tissue level.

**Prediabetes:** condition characterized by impaired fasting glucose (IFG) or impaired glucose tolerance (IGT); however blood glucose levels at this stage have not yet reached diabetic diagnostic levels (American Diabetes Association, 2013). Prediabetes is diagnosed when IFG levels fall between 100 -125 mg/dL and/or when blood glucose levels fall between 140 -199 mg/dL after an impaired glucose tolerance IGT test (2-hour post-load plasma glucose)
CHAPTER II

LITERATURE REVIEW

Overview of Type 1 and Type 2 Diabetes Mellitus

Diabetes Mellitus (DM) is widely recognized as a significant health problem in the United States. DM is a group of metabolic disorders identified by higher than normal blood glucose levels (Raymond & Escott-Stump, 2008). DM occurs when the body’s pancreas does not produce insulin (type 1 diabetes mellitus), and/or when the body does not respond well to insulin secretion (type 2 diabetes mellitus). Insulin is a protein hormone made exclusively in the pancreas by beta cells (β-cells) of the islets of Langerhans. Insulin plays a crucial role in the regulation of blood glucose uptake at the cellular level and is immediately released into the blood by pancreatic β-cells as glucose concentrations increase (Murray, Granner, & Rodwell, 2006). Insulin thereby stimulates the uptake of glucose into adipose tissue (AT) and skeletal muscles (SM) where it is stored or utilized for energy. Insulin regulates glucose uptake into AT and SM by recruiting glucose transporter protein 4 (GLUT 4), which move from the interior of the cell to the cell surface, allowing glucose to enter the cells by facilitative diffusion (Murray et al. 2006).

Defects in the insulin response that normally occurs during a fed state cause disturbances in carbohydrate, lipid and protein metabolism, thereby affecting the use and storage of these macronutrients. Abnormalities in metabolism, particularly carbohydrate metabolism, cause hyperglycemia. Hyperglycemia is associated with serious health conditions, which can significantly decrease life expectancy for individuals with poor blood glucose control.
Proper management of glycemic control is important in preventing and decreasing health risks associated with the disease (Raymond & Escott-Stump, 2008).

There are many different types of diabetes mellitus. The most common types include the following: Type 1 diabetes mellitus (T1DM), gestational diabetes mellitus (GDM), and type 2 diabetes mellitus (T2DM) (Raymond & Escott-Stump, 2008). Prediabetes has also gained attention over the past decade since large randomized clinical efficacy trials have demonstrated that behavioral lifestyle interventions can prevent or delay the onset of T2DM in high-risk individuals. Since diabetes prevention is critical in reducing health disparities, this review will focus on T2DM prevention in the prediabetic state.

**Overview of Prediabetes**

Due to the devastating impact associated with type 2 diabetes, preventing diabetes has gained recognition over the last decade. Prediabetes is a condition characterized by impaired fasting glucose (IFG) or impaired glucose tolerance (IGT); however blood glucose levels at this stage have not yet reached diabetic diagnostic levels (American Diabetes Association, 2013). Prediabetes is diagnosed when IFG levels fall between 100 - 125 mg/dL and/or when blood glucose levels fall between 140 - 199 mg/dL after an impaired glucose tolerance IGT test (2-hour post-load plasma glucose) (American Diabetes Association, 2013).

Numerous studies have shown that blood glucose levels in the prediabetic range increases the risk for CVD and microvascular diseases. The relationship between IFG and PPG with incidence of cardiovascular disease events has been well documented in individuals with prediabetes (Charpentier, Riveline, Dardari, & Varroud-Vial, 2006).
Compared to IFG, “glucose excursions” in the postprandial state that eventually lead up to the progression of type 2 diabetes have shown to cause more oxidative stress and poses the greatest risk for developing CVD and CVD related deaths (Gavin, 1994). In the cardiovascular health longitudinal study, subjects (n=4515) with glucose intolerance had a 1.22 higher relative risk for CVD mortality compared to subjects who had normal glucose (Charpentier et al., 2006). Studies examining the association between blood glucose and CVD have also compared glycosylated hemoglobin (HbA1c) with CVD risk. For example, the National Health and Nutrition Examination Survey (NHANES) found that only modest increases in HbA1c were associated with peripheral arterial disease (Bianchi, Miccoli, Penno, & Del Prato, 2008). In addition, Selvin et al. (2010) studied the association between HbA1c and CVD, and found that nondiabetic adults with HbA1c levels between 5.5% and less than 6.5% were at greater risk of risk of developing diabetes and CVD compared with levels less than 5.5% after adjusting for fasting glucose and key CVD risk factors (Selvin et al., 2010). Microvascular diseases such as neuropathy, proteinuria, and retinopathy have also found to be present in individuals with IGT (Singleton, Smith, Rusell, & Feldman, 2003). In the diabetes prevention study, there was only a 4.7% difference in cases of diabetes related retinopathy among subjects with diabetes (12.6%) and subjects with prediabetes/IGT (7.9%) (Diabetes Prevention Research Group, 2007). Overall, prediabetes is a serious condition that poses health risks similar to that of type 2 diabetes.

Like type 2 diabetes, the prevalence of prediabetes has increased within the past decade. According to the U.S. Census data, prediabetes has increase from 79 million to (2005-2009 data) to 86 million (2009-2012 data) in adults 20 years of age or older, and is
more prevalent among individuals aged 65 years and older (Centers for Disease Control, 2012). Similar to type 2 diabetes, the prevalence of prediabetes is also higher among ethnic subgroups. An analysis conducted by Bullard et al. (2013) looked at data from the NHANES between 1999-2010, and examined the HbA1c and IFG levels of 19,182 individuals older than 12 years of age. HbA1c levels in the range of 5.7% to less than 6.5% were considered criteria to meet prediabetes (a range found to increase CVD risk factors). Based on the HbA1c criteria, the prevalence of prediabetes increased from 1999-2002 to 2007-2010 in non-Hispanic whites (8.5–15.9%), non-Hispanic blacks (16.3–28.3%), and Mexican Americans (9.7–17.1%), however prevalence related to IFG remained unchanged (23.8–25.9%). Bullard and colleagues concluded that diabetes prevention efforts are needed to identify and treat at risk subgroups to prevent the projected increase in prevalence of prediabetes (Bullard et al., 2013).

Prediabetes often goes undiagnosed until individuals start displaying symptoms of type 2 diabetes (American Diabetes Association, 2009). Recent estimates have concluded that 9 out of 10 people do not know that they have prediabetes (Centers for Disease Control, 2012). Undiagnosed prediabetes presents a serious missed public health opportunity for diabetes prevention since 15-30 percent of individuals with prediabetes will develop type 2 diabetes within 5 years (Centers of Disease Control, 2014) and 70% with prediabetes will eventually develop the disease in their lifetime (Knowler et al., 2002). Risk factors associated with prediabetes are similar to those of type 2 diabetes and include the following: 45 years of age or older; overweight or obese; hypertension; family history of diabetes; racial or ethnic background of either African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander; gestational
diabetes; birthing a baby weighing nine pounds or more; and physical inactivity of less
than three times a week (National Diabetes Information Clearinghouse, 2011). Taking
active steps to improve controllable risk factors such as weight and physical activity is
critical in preventing prediabetes from progressing to type 2 diabetes. The current
American Diabetes Association recommendations for prediabetes management include
modest weight loss (7% of initial body weight), moderate exercise (150 min per week),
consideration of metformin (for those with BMI >35 kg/m², age <60 years, or women
with a history of gestational diabetes mellitus), and treatment of modifiable CVD risk
factors (American Diabetes Association Standards of Medical Care, 2013).

**Diabetes Prevention Clinical Efficacy Trials**

The findings of three major diabetes prevention studies have set the precedent for
the current prediabetes management recommendations in the U.S. These large
randomized clinical efficacy trials conducted in diverse countries and populations
demonstrated that type 2 diabetes is preventable in high risk populations through
adopting a lifestyle that involves changing dietary and physical activity behaviors, and
loosing a modest amount weight (Pan et al., 1997; Toumilehto et al., 2001; Knowler et al.,
2002). Despite the relatively short duration of lifestyle interventions offered in these
clinical trials, long-term outcomes studies of 5 to 20 years have shown a carryover effect
on diabetes incidence (Knowler et al., 2009; Uusitupa et al., 2009; Li et al., 2008). While
lifestyle interventions have demonstrated improvements in cardiometabolic risk factors
(e.g. blood pressure and triglycerides), CVD related morbidity and mortality rates have
not reached statistical differences between intervention and placebo groups (Uusitupa et
al., 2009; Li et al., 2008). The three major diabetes prevention studies are briefly
described below. The study designs and populations differ in each of these prevention
interventions, however the primary outcomes of diabetes incidence are reported in all of
these studies. The Da Qing China study was one of the first randomized controlled trials
to demonstrate that a lifestyle intervention could reduce the incidence of diabetes by
25% to 50% in individuals with IGT. Pan et al. (1997) conducted a 6 year study to
investigate the combined and separate effects of diet and exercise on the incidence of
diabetes in lean (BMI <25) and obese (BMI >25) men and women over the age of 25
years of age with IGT. Subjects (n=533) were assigned to 33 clinics and the clinics were
randomized to implement a diet only, exercise only, diet-exercise combined, or no study
intervention. Individual and group-based dietary and physical activity interventions were
conducted weekly (for 1 month), monthly (for 3 months), and every 3 months (for six
years). At the 6 year follow-up, the incidence of diabetes was significantly higher in the
control group (68%) compared to all three of the intervention groups (exercise = 41%,
diet and exercise =46%, and diet =44%) (P < 0.05). Despite relatively low weight loss
(no change in lean subjects and less than 1kg in overweight subjects) there were lower
incidences of diabetes (except lean diet group) in both BMI categories compared to the
control groups (P < 0.05), however the relative rates of diabetes occurrence were similar
in both the obese and lean intervention groups. This possibly suggests that weight loss
alone may not be the only lifestyle factor involved in diabetes prevention and is a direct
result of changes in dietary and physical activity factors.

At the 20 year follow-up study, the incidence of diabetes increased in the control
group from 68% to 93% and from 41-46% to 80% in all intervention groups combined.
Although this was a relatively high increase for both study groups, significant difference
in incidence of diabetes was found between the control and diet-exercise group, which had a 43% less incidence rate at the 20 year follow-up (Li et al., 2008). In terms of cardiovascular risk, Li and colleagues also examined whether the lifestyle intervention (diet alone, exercise alone, and exercise-diet) reduce the risk or CVD and mortality at the 20 year follow up study. While a 17% reduction in CVD related deaths was found in the three intervention groups combined, this was not significant from the control group, but may suggests a potential benefit of the lifestyle interventions (Li et al., 2008).

Another large randomized control trial conducted in Finland also found that an intensive lifestyle intervention could reduce the incidence of type 2 diabetes in high risk individuals. Tuomilehto et al. (2001) conducted a 6-year diabetes prevention study (DPS), and investigated the combined effects of an intensive diet-exercise program aimed at moderate weight reduction (5%) on incidences of diabetes in middle aged (mean age, 55 years) overweight (mean BMI > 25) men and women (n=522) with IGT. Subjects were randomized to either an intensive intervention group or control group. The intensive group protocol involved individual and group-based intervention sessions which were conducted by a nutritionist at 1-2 weeks, 5-6 weeks, 3, 4, and 6 months and every three months for 6 years. Weight loss at the end of 2 years was 3.5±5.5kg in the intervention group and 0.8±4.4kg in the control group (P<0.001). Changes in fasting plasma glucose, IGT, serum insulin, triglyceride concentrations and blood pressure also significantly improved at two years. After four years the incidence of diabetes was 11 percent in the intervention group compared to 23 percent in the control group, and at the end of the trial the risk of diabetes was reduced by 58 percent (P<0.001) in the intervention group (Tuomilehto et al., 2001).
At the 7 year DPS follow-up analysis, the decrease in incidence of type 2 diabetes persisted (4.3 and 7.4 per 100 persons per year) in the intervention and control group with a relative risk reduction of 43% (p=0.0001) in the intervention group compared to 58% at year four (Lindström et al., 2006). Subjects who did not develop type 2 diabetes were more likely to have achieved four out of the five intervention goals i.e., weight loss of greater than 5%, fat intake of less than 30% of total energy, saturated fat intake of less than 10% of total energy, dietary fiber intake of greater or equal to 15 g/1,000 kcal, and physical activity of at least 4 h/week (Tuomilehto et al., 2001).

In terms of CVD morbidity and mortality, a 10-year follow-up study of the DPS did not find that total mortality (2.2 vs. 3.8 per 1,000 person-years) and cardiovascular morbidity (22.9 vs. 22.0 per 1,000 person-years) differed between the intervention and control groups (Uusitupa et al., 2009). However, when DPS subjects were compared to a Finnish population cohort group, an adjusted hazard ratios analysis showed that DPS subjects with IGT at baseline had lower total mortality (HR= 0.21) compared to the cohort group (HR= 0.39). In addition, DPS subjects had a lower cardiovascular morbidity (HR=0.89) compared to the cohort group (HR=0.87). The authors indicate that the difference in mortality between the DPS and cohort group may be due to a lower initial CVD risk profile (lower blood pressure, TG, and serum insulin) and consistent follow-up (study related follow-up) (Uusitupa et al.,2009).

The Diabetes Prevention Program (DPP), a U.S. based study, was the first randomized controlled trial to compare the efficacy and safety of a hypoglycemic oral medication to a lifestyle intervention on incidence of type 2 diabetes (Knowler et al., 2002). The DPP was the largest of the three diabetes prevention trials involving 27
centers and 3234 participants. Participants had a mean age of 51 years, and recruitment samples consisted of minority groups (45%; n=508 Hispanics) elderly individuals ≥ 60 years of age (20%; n=648), and both men and women (68% women; n=1940). Participants were followed for approximately 3.2 years.

Participants with IFG and IGT were randomized to three interventions: an intensive lifestyle intervention or standard lifestyle recommendation (one time intervention) plus metformin (850 mg twice daily) or placebo. The intensive lifestyle intervention consisted of 16 individualized sessions delivered over 24 weeks (core sessions) with two physical activity session offered weekly. A 6-month maintenance phase (post core sessions) was offered every other month and phone contacts occurred monthly. The intensive lifestyle intervention goals were to achieve a 7% weight loss, engage in moderate intensity greater or equal to 150 min per week (30 minutes a day on a least 5 days a week), and change dietary behaviors by reducing fat and calorie intake (Knowler et al. 2002). The DPP study design and goals are displayed in Table 1. After the core sessions (24-weeks) the average weight loss was significantly higher in the lifestyle intervention group (5.6kg) compared to the metformin group (2.1kg) and placebo group (0.1) (P<0.001). Incidence of diabetes at the follow up (2.8 years) was lowest in the lifestyle intervention group (4.8 cases per 100 person) compared to the metformin group (7.8 cases per 100 persons) and placebo group (11.0 cases per 100 persons). The incidence of type 2 diabetes was 58% lower in the lifestyle intervention group and 31% lower in the metformin group compared to the placebo group, suggesting that the lifestyle intervention was more effective at preventing type 2 diabetes compared to metformin and placebo group. Another major finding of the DPP
was that the lifestyle intervention was effective for all subgroups and did not differ based on gender, age, and race or ethnicity. Compared to metformin, the lifestyle intervention was more effective for individuals 60 years and older compared to younger individuals. The DPP 10 year follow up study also showed that the risk of type 2 diabetes significantly decreased in all groups regardless of ethnicity, age or gender, and demonstrated that the potential for reducing health disparities in high-risk populations is possible with weight loss (Hamman et al., 2006).

To test the long-term effects of the DPP intervention, the Diabetes Prevention Program Outcomes Study (DPPOS) recruited participants from the original DPP and offered them a 16-session group based lifestyle intervention over 24 weeks as a bridge protocol. A protocol was developed for maintenance sessions (post core sessions), which were offered over the course of the 6 year study period (Knowler et al., 2009). A total of 2665 participants from the original study (lifestyle group 40%; metformin group 58%; placebo group 57%) enrolled in the DPPOS.

During the DPPOS follow-up study, the original lifestyle group lost an average of 7kg, but then regained approximately 1 kg at the end of the DPPOS study. This was found to be 2kg less than what they weighed at the start of the original DPP. The metformin group and placebo group initially lost weight during the DPPOS and then regained weight similar to baseline levels at the final follow-up. However, older participants (aged 60–85 years) in both the metformin and placebo groups had a decrease in weight. In terms of diabetes incidence, the differences in diabetes incidence rates, which were seen among the treatment groups in the original DPP at 2.8 years, did not persist and were similar between all groups at 10 years. The cases of diabetes were
highest in the lifestyle group (5.9 per 100 person-years) compared to the metformin group (4.9 per 100 persons-year) and the placebo group (5.6 per 100 persons-years). However, the cumulative incidence of diabetes was lowest in the lifestyle intervention (34%) and metformin group (18%) compared with placebo group (Knowler et al., 2009).

Numerous explanations were proposed for the DPPOS findings. The authors concluded that the similar incidence of diabetes between the groups was not due to a rebound effect in the lifestyle group since the cases of diabetes in this group were fairly stable from the initial randomization period at the start of the original DPP (4.8 vs 5.9 cases per 100). One explanation for the decrease in incidence of type 2 diabetes in the metformin and placebo group was the possibility that the lifestyle intervention offered to all groups was particularly effective for elderly individuals who had a decrease in weight during the study period. This finding suggests that the lifestyle group may be particularly relevant to older and elderly individuals (Knowler et al., 2009).

Cardiometabolic risk factors were also assessed in the DPPOS study (Orchard et al., 2013). CVD risk factor measures improved in all groups after the 10 year follow-up. Improvements in lipid profiles were found for the following CVD risk factors: LDL cholesterol (-0.51 to -0.6 mmol/l), triglycerides (-0.23 to -0.25 mmol/l), and HDL cholesterol (0.14 to 0.15 mmol/l) with no differences among the means for all groups. Reductions in both systolic (-2 to -3) and diastolic (-6 to -6.5 mmHg) blood pressure were also found in all groups. Despite the similar group effects for lipid and blood pressure measures, medication use to manage lipid profiles (P<0.012) and blood pressure (P<0.09) were significantly lower for the lifestyle group suggesting this group was able to achieve similar results with lower medication use. Medication use did improve fasting blood
glucose and HbA1c levels more so in the metformin group. These findings indicated that although the DPPOS intervention had little effect of CVD risk factors, it is difficult to discern future CVD morbidity and mortality outcomes. Due to the smaller sample size in the DPPOS compared to the original DPP, CVD related mortality and morbidity were not assessed in this study (Orchard et al., 2013).

Overall, diabetes prevention interventions show promise in reducing the incidence of type 2 diabetes long-term, and have been particularly effective in elderly individuals. Despite the relatively short duration of the intervention period in these clinical efficacy studies, outcomes studies have shown that lifestyle interventions produce a long-term effect on the cumulative incidence of diabetes. This carryover effect was seen in the DPPOS where cases of diabetes were slightly higher in the lifestyle intervention (5.9 cases per 100 persons-year) compared to the metformin intervention (4.9 cases per 100 persons-year) and placebo group (5.6 cases per 100 persons-year), but cumulative incidence of diabetes was lowest in the lifestyle intervention (34%) and metformin group (18%) compared with placebo group at the 10 year follow-up (Knowler et al., 2009). This carryover effect occurred in the DPPOS despite the lifestyle group regaining weight and achieving a 2kg weight loss difference from baseline in the original DPP. This phenomenon, was also seen in the Da Qing study where incidence of diabetes was 27% less in the exercise-diet group compared to the control group despite relatively low weight loss (no change in lean subjects and less than 1kg in overweight subjects) (Pan et al., 1997). Small changes in weight loss could potentially have great impacts on incidence of diabetes. The DPP trial showed that for every kilogram of weight loss, diabetes incidence was reduced by 16% (Knowler et al., 2009). According to
Tuomilehto et al. (2001), the interaction between multiple lifestyle factors e.g. physical activity and fiber intake, play critical roles in the prevention of diabetes and should all be given equal importance rather than weigh loss alone (Tuomilehto et al., 2011).

Table 1

Diabetes Prevention Program Components and Study Design

<table>
<thead>
<tr>
<th>Diabetes Prevention Program Components</th>
<th>Diabetes Prevention Program Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss goal</td>
<td>7% of initial weight</td>
</tr>
<tr>
<td>Physical activity goal</td>
<td>150 minutes per week</td>
</tr>
<tr>
<td>Intervention facilitator design</td>
<td>Individual contacts</td>
</tr>
<tr>
<td>Number of core sessions/contacts (0-6-months)</td>
<td>16 sessions over the first 24 months</td>
</tr>
<tr>
<td>Number of post-core sessions/contacts (7-12 months)</td>
<td>8 sessions over next 24 months (4 in person contacts and 4 phone contacts). *A minimum of one in person contact every two months.</td>
</tr>
<tr>
<td>Refresher groups/campaigns</td>
<td>3 times per year after the first 6 months</td>
</tr>
<tr>
<td>Physical activity sessions (supervised)</td>
<td>Offered 2 times per week throughout the entire trial</td>
</tr>
<tr>
<td>Nutrition Intervention</td>
<td>Self-selected diet with fat gram goals based on initial weight and set calorie goal if weight loss not achieved.</td>
</tr>
</tbody>
</table>

Behavioral Framework

- Transtheoretical Model
- Social Cognitive Theory
- Self-management

Incentive Strategies

- Basic tool box
- Advanced tool box


The Diabetes Prevention Program (DPP) Progress

While it has been over a decade since the DPP clinical trial provided evidence-based knowledge on the prevention of diabetes, this scientific discovery has yet to significantly reduce the incidence and prevalence of type 2 diabetes in the United States.

As mentioned prior, the Healthy People 2010 goals were not met and diabetic related
health disparities continue to rise in the United States. Unfortunately, scientific knowledge commonly fails to translate quickly into improved public health outcomes - a phenomenon well known among the scientific community. The “gap” between scientific discoveries and improved health outcomes is not a new topic of discussion. In 2001, the Institutes of Medicine (IOM) acknowledged the gap between how health care practices could improve if informed by scientific knowledge and how health care is actually practiced. The IOM described this issue as a “chasms” in health care system (IOM, 2001). This gap has been well documented in the field of type 2 diabetes for decades. As early as the 1990s, United States national data indicated a discrepancy between recommended diabetes care and the actual care patients received (Saaddine et al., 2002). In the most recent National Health and Nutrition Examination Survey and the Behavioral Risk Factor Surveillance System, Ali et al. (2013) reported that an incremental improvement in diabetes quality of care, however indicated that over half of individuals with diabetes (33.4 to 48.7%) still did not meet goals for critical diabetes related risk factors such as glycemic control, blood pressure, or LDL cholesterol levels. (Ali et al, 2013). In relatively recent years Green et al. (2009) referred to this phenomenon as a leaky pipeline, suggesting that it could take approximately 17 years for 14% of research to impact health care practices. For example, some factors that affect movement from research to practice in the pipeline range from publication, to textbook recommendations, to how evidence fits into real-world practice (Green et al., 2009).

Over the past five years, efforts to translate the DPP intervention into a variety of settings have resulted in substantial progress and widespread dissemination of the DPP are seemingly closer than not, to reaching the end of the pipeline. The DPP has gained
recognition over the last several years prompting great interest in behavioral lifestyle interventions for diabetes risk reduction. The new Healthy People 2020 objectives acknowledged the DPP as an emerging public health approach that, “may deserve monitoring at the national level” (http://www.healthypeople.gov/2020/topics-objectives/topic/diabete). Since 2008, over 20 original DPP translation studies have been published on the adaptation of the DPP lifestyle intervention, which has led to multiple systematic literature reviews (Whittemore, 2011) and critical discussions (Pagato, 2011) on this specific program. The DEPLOY study in particular, has made great strides in developing and evaluating an adapted DPP model that shows great promise in reaching nationwide dissemination. The DEPLOY model known as PLAN4WARD (P4W) is a group-based intervention that was originally tested in two Young Men’s Christian Association (YMCA) sites and has shown to be cost-effective in part due to the delivery of the intervention by wellness instructors rather than specialty professionals (Ackermann, Finch, Brizendine, Zhou & Marrero, 2008). As a result of the DPP clinical trial and subsequent DPP translation research efforts, the Centers for Disease Control and Prevention (CDC) has taken an active stance on diabetes prevention and recently launched the National Diabetes Prevention Program (NDPP) initiative (http://www.cdc.gov/diabetes/prevention/) through a partnership with the YMCA. The initiative encourages organizations to collaborate with stakeholders e.g., federal agencies, community-based organizations, employers, health care professionals, and academia to build a provider network aimed at diabetes prevention in the United States. Those interested in delivering the lifestyle intervention must demonstrate that the delivery of the
DPP meets CDC Diabetes Prevention Recognized Program (DPRP) Standards before gaining full recognition (http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf). For example, organizations must meet fairly strict criteria similar to the DPP clinical efficacy trial e.g., program intensity, duration (one year) and attendance as well as documentation of weight loss (5%) and physical activity logs to gain full recognition. According to the CDC, over 625 organizations currently offer the program nationwide. In California, a total of 18 organizations offer the program, all of which are in “pending” status and have not yet met DPRP approval (https://nccd.cdc.gov/DDT_DPRP/Registry.aspx). Currently, the DPP has not yet been publicly recognized by the Centers for Medicare and Medicaid Services (CMS), however in 2011, “intensive behavioral therapy” for obesity was deemed a reimbursable intervention in the primary care setting. Given the numerous barriers that hinder the translation of research into practice, the progress that has been made in this area of study on one hand has succeeded in numerous areas that otherwise often fail. At this stage of progress, the DPP has great potential to reduce diabetes risk and obesity related health issues. However, it remains unknown as to whether the implementation of this program in real-world settings, can reproduce the results obtained in the DPP clinical efficacy trial. Therefore, further type 2 translation research efforts are needed to identify the best methods of implementing the DPP into community and clinical settings.

What Is Translational Research?

Type 2 translation research can help inform the process of moving evidence-based knowledge into practice, and is important in all areas of research whether it be pharmaceutical testing or intensive behavioral lifestyle interventions
Without type 2 translation research, scientific findings remain stagnant and evidence-base knowledge will not reach patients and populations who can benefit from these discoveries. While each research discipline faces different barriers in translating evidence into practice, a common question that arises in this type of research is, “Will the evidence and intervention be applicable to the new setting?” Type 2 translation research helps address this common question (Brownson et al, 2012).

The findings of the DPP clinical trial have provided the foundation for conducting Type 2 translation research in the field of diabetes prevention. According to the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program, there are two areas of translation research, which are collectively referred to as translational research. While there has been discussion on how to clearly define this area of study, the NIH provided the following definition in 2006, for organizations interested in applying for CTSA grants:

“Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science” (National Institutes of Health, 2007).

The current CTSA translational research model includes a two-phase translation process that falls along one continuous spectrum. The model shown in Figure 1,
demonstrates how the research process moves across the continuum beginning with basic laboratory discoveries to patient-centered research (phase one), and from patient-centered research to clinical and community health practice (phase two) (National Institutes of Health, 2014). This particular model works in a multidirectional fashion by supporting an interaction between each phase of the research process. For example, observations gained in clinical research (patient-centered research) may need to go back to the laboratory for further testing before a clinical trial can resume. This interaction ensures that knowledge gained at each of the different phases is shared among researchers, so that translation research successfully progresses throughout the entire process. Depending on the field of study, translation research encompasses a wide range of research topics, from diagnostics to medical procedures to behavioral changes.

Type 1 research (T1) and Type 2 research (T2). T1 research is often described as moving from the “bench to-bedside.” This research process starts with basic laboratory sciences (the bench), and transfers knowledge gained from these discoveries to develop and test the efficacy of new treatment options (e.g., medications, products and devices) or preventative interventions on patients in clinical trials (the bedside) (Sussman, Valente, Rohrbach, Skara, & Pentz, 2006; Brownson et al., 2012). In short, the T1 research spectrum begins with fundamental research and ends with efficacy research. Type 2 research is referred to as moving from the “bedside-to-practice.”
The two phases of research proposed by the NIH are commonly referred to

The T2 research process strives to ensure that evidence-based knowledge discovered from efficacy research, reaches widespread use by the target population. T2 research aims to integrate efficacious programs, products and services into policy and practice and involves the following four areas of research: (1) effectiveness research; (2) implementation research; (3) dissemination research and (4) diffusion research. Both T1 and T2 research are essential to bridging the gap between science and practice for the primary purpose of improving health outcomes (Sussman et al. 2006; Brownson et al. 2012).

There has been discussion on how best to define the different phases of translational research. To help clarify the term and improve translation efforts, some researchers have suggested expanding the definition of translational research to include a Type 3 (T3) and Type 4 (T4) translation phase. For example, Westfall,
Mold, & Fagnan (2007) recreated the traditional model to include a T3 loop, which translates “practice-based research” findings to clinical practice through dissemination and implementation (D&I) research efforts (Westfall et al., 2007). However, this particular model, while frequently referenced in the literature, has been criticized for being clinically driven and physician focused (Woolf, 2009). In recent years, Rubio et al. (2010) suggested ways to improve the NIH definition of translational research by adding a T3 step in the model, which is the first model to support a multidirectional interaction between laboratory-based research and population-based research (Rubio et al., 2010). In addition, T4 research has also been added to the continuum to evaluate how practice impacts health outcomes at the public health or population-level (Khoury et al., 2007). As a result of these proposed definitions, some universities (Tufts University and UCLA) who are part of the CTSA national consortium have adopted the working definitions of T3 and T4 research and have provided examples of what type of studies and goals constitute T1, T2, T3, and T4 research (Tufts University, n.d; UCLA, 2013). To confuse matters, some researchers do not consider effectiveness research as a part of the NIH translational research model and process (Schillinger, 2010). Therefore, translation research is sometimes viewed as an extension of effectiveness research and only considers the components of D&I as part of the translation process (Schillinger, 2010). However, due to the lack of consensus among the science community and federal funding agencies (e.g., NIH and CDC) regarding where the different phases of translation research fall along the spectrum, this review considers effectiveness research as part of the T2 translation process (Brownson et al., 2012). This review
will adopt the NIH model (Figure 1) and focus on the second area of translation or Type 2 translation research (T2) in the field of diabetes prevention.

Based on the NIH translational research model, the DPP clinical efficacy trial fits into the “patient-centered research” phase of the diagram allowing for T2 research to take place (Figure 1). Specific to the DPP and the field of diabetes prevention, T2 research investigates how to effectively deliver the DPP intervention to patients and communities in “real-world” settings, with the goal of reaching sustained adoption in practice and policy. Ideally, the progression of T1 to T2 research involves utilizing efficacy research (T1) findings to develop and conduct effectiveness research (T2), which then leads to dissemination (T2) and implementation (T2) research (Brownson et al., 2012). Diffusion research (T2) builds upon dissemination and implementation research as well as other strategies (e.g., marketing and policies), and focuses on bringing the implemented intervention to a state or national level.

Table 2, on the following page provides definitions of research terms pertaining to T1 and T2 research. The CDC initiative is an example of dissemination and implementation research (D&I) and diffusion research, and for the most part in its preliminary stages.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T1</strong></td>
<td><strong>Fundamental or Basic research</strong> develops laboratory-based, etiologic models to provide theoretical explanation for generic or more specific phenomena of interest.</td>
</tr>
<tr>
<td><strong>T1</strong></td>
<td><strong>Efficacy research</strong> refers to the intervention’s ability to do more good than harm among the target population in an ideal setting (e.g., randomized clinical control trial or community-level trial).</td>
</tr>
<tr>
<td><strong>T2</strong></td>
<td><strong>Effectiveness research</strong> refers to the intervention’s ability to do more good than harm for the target population in a real world setting.</td>
</tr>
<tr>
<td><strong>T2</strong></td>
<td><strong>Implementation research</strong> is the systematic study of how a specific set of activities and designed strategies are used to successfully integrate an evidence-based public health intervention within specific settings (e.g., primary care clinic, community center, school).</td>
</tr>
<tr>
<td><strong>T2</strong></td>
<td><strong>Dissemination research</strong> is the systematic study of how the targeted distribution of information and intervention materials to a specific public health audience can be successfully executed so that increased spread of knowledge about the evidence-based public health interventions achieves greater use and impact of the intervention.</td>
</tr>
<tr>
<td><strong>T2</strong></td>
<td><strong>Diffusion research</strong> is the systematic study of the factors necessary for successful adoption by stakeholders and the targeted population of an evidence-based intervention which results in widespread use (e.g., state or national level) and specifically includes the uptake of new practices or the penetration of broad scale recommendations through dissemination and implementation efforts, marketing, laws and regulations, systems-research and policies.</td>
</tr>
</tbody>
</table>

Barriers to Translational Research

Facilitating the progression of T1 to T2 research has been a universal challenge. There are numerous complex barriers that hinder the translation of evidence-based efficacy research (T1) to effectiveness and D&I research (T2). These include but are not limited to the following factors: research design, limited resources, provider training, organizational barriers, and social, cultural and behavioral factors (Garfield et al., 2003). These multifactorial barriers play a role in essentially two areas of type 2 translation research 1) whether efficacy interventions can progress to effectiveness and D&I research and 2) whether implementation of the intervention produces desired outcomes in applied settings (Brownson et al. 2012).

A common issue that has consistently occurred over time is the issue of internal versus external validity (Glasgow, Lichtenstein, & Marcus, 2003). For example, efficacy trials, such as the DPP, are important in establishing internal validity or causal inferences, such as evidence-based information on the prevention of diabetes however, these tightly controlled study designs delivered under optimal conditions have proven challenging to implement in real-world settings (Glasgow et al, 2003). Nevertheless, transitioning from efficacy research to effectiveness research is necessary to establish external validity and test whether an intervention like the DPP, can be generalized to a large population under less ideal conditions.

In recent years, strategies to design studies that test both internal and external validity as well as implementation strategies have gained popularity (Brown et al., 2009). To address the gap in clinical science and practice, the NIH clinical and translational research initiative, currently uses a research model that incorporates basic research,
efficacy research, and implementation research (service system research) in their study
designs (Westfall et al, 2007). Furthermore, frameworks such as the PRECEDE-
PROCEED (Predisposing, Reinforcing, and Enabling Construct in
Educational/environmental Diagnosis and Evaluation – Policy, Regulatory and
Organizational Constructs in Educational and Environmental Development) (Green,
2005) and RE-AIM models (Reach, Effectiveness, Adoption, Implementation, and
Maintenance) (Jilcott, Ammerman, Sommers, & Glasgow, 2007) are being commonly
used in the planning and evaluating of D&I research (Brownson et al, 2012). The RE-
AIM model which was proposed by Glasgow et al. in 2003, was originally developed to
address the long-standing issue of internal versus external validity, and provide an
evaluation model to improve the implementation of individualized behavioral
interventions pertaining to diabetes management (Glasgow et al., 2003). In a recent
systematic review conducted by Whittemore (2011) the RE-AIM model was used to
evaluate the current standing of DPP translation research protocols (Whittemore, 2011).

Limited funding is a predominate barrier that impedes type 2 translation research on
multiple levels. In a commentary by Steven H. Woolf, titled “The Meaning of
Translational Research and Why It Matters, Woolf (2008) points out that large
organizations such as the Agency for Healthcare Research and Quality (AHRQ) and the
NIH, prioritizes T1 research and offers significantly more grant funding to the “bench-to-
bedside” enterprise, compared to T2 research (Woolf, 2008). For example, in 2002
funding for health services research, which involves “dissemination” research,
represented 1.5% of funding compared to biomedical research (Woolf, 2008). Woolf
(2008) argues, that more funding and attention to T2 research are needed to gain a return
on the investment of T1 research since this phase of research is essentially responsible for closing the gap between research and improved health outcomes. T2 research strives to ensure that knowledge and new treatments are implemented with fidelity and are made available to patients and populations that will benefit from the discovery. T2 research, as Woolf states, has the ability to save more lives and therefore must come out from under the shadows of T1 research and redefine itself.

Fortunately, as mentioned prior, the NIDDK provided funding to conduct two large randomized control DPP T2 research studies (Fradkin & Rodgers, 2013) and the CDC funding has enable D&I and diffusion research of the program. However, despite this funding, costs associated with implementing certain research protocols or interventions present another cost related barrier to T2 research. For example, the DPP lifestyle intervention was quite costly to implement which has raised concerns about the sustainability of the program (Venditti & Kramer, 2012). In a cost analysis conducted by Herman et al., the lifestyle group cost approximately $1,399 per participant to implement in the first year alone, which was more costly than the metformin group ($1019) or the placebo group ($43) (Herman et al. 2003). While the cost of the program slightly decreased in the second and third year of the study, the higher cost associated with the lifestyle group was due to the expense of individual counseling delivered by behavioral experts e.g., psychologists and registered dietitians, which accounted for 54% of this cost ($750.00). Due to concerns related to funding and staffing, much of the recent T2 DPP research has sought to discover ways to deliver the DPP in a less costly manner, while maintaining the fidelity and outcomes of the program.

Aside from the issue of internal and external validity in research study designs and
limiting funding to carry out T2 research, there are other common barriers that prevent scientific discoveries from reaching practical applications. According to Orlandi (1987) barriers to T2 research or more specifically dissemination research are multifactorial, and influenced by the interaction between the original developers of the research, the providers who deliver the information e.g., physicians and health care workers, and the “decision-makers” at the organizational setting e.g. administrators or physicians in private practice (Orlandi, 1987). All these factors can impede the transfer of “innovations” (new knowledge, ideas, and services) to those who can benefit from them. At the organizational level, barriers to T2 research can occur when “decision-makers” in health care settings do not adopt and allow patients access to specific “innovations” or do not adequately inform health care providers that new knowledge is available. This interaction between the organization, health care provider, and research developer, creates a complex system to move research into practice (Orlandi, 1987).

Decisions to adopt new “innovations” by organizations are based on a variety of factors such as financial reimbursement, organizational priorities, belief of program effectiveness and lack of standardization (Orlandi, 1987). Prevention and health promotion interventions involving lifestyle counseling and behavioral issues have been particularly challenging to implement into practice due to the lack of standardization. Unlike standardized medical interventions, such as surgery or medication dosing, the nature of behavioral interventions are not as easily transferable to multiple settings and broad based populations (Glasgow et al., 2003). A major objective of T2 research therefore, strives to identify settings that are better suited to transfer knowledge to target groups. In the case of the DPP, it has been suggested that community settings, may be a
better organizational fit for intensive lifestyle programs, compared to health care settings (Ackermann et al., 2008).

Health care providers play critical roles in the knowledge transfer process once organizations decide to adopt “innovations.” Orlandi (1987) refers to providers as the “gatekeepers” because they control both the dissemination process through the organization and the implementation process, by transferring knowledge and services directly to patients and clients (Orlandi, 1987). Despite the availability of innovative knowledge, barriers to T2 translation often occur at the provider level due to inadequate intervention approaches that are influenced by the beliefs, attitudes and knowledge of the provider (Nam, Chesla, Stotts, Kroon, & Janson, 2011). These barriers have been particularly well documented and promoted in the field of diabetes self-management at the patient level, however sufficient evidence suggests that barriers to adequate diabetes care also stems from challenges faced by providers. For example, in an early study conducted by Larme & Pugh (1998), providers viewed diabetes as more difficult to treat than hypertension (p = .03), and a qualitative analysis revealed that providers attitudes lacked confidence in the efficacy of diabetes treatment as well as their own capabilities to apply recommended treatments into practice (Larme & Pugh, 1998). In contrast, Dalewitz, Khan & Hershey (2000) assessed the general perspective and beliefs of physicians' regarding diabetes and found those physicians’ perceived patients as non-adherent, and attributed poor glycemic control to patients lack of motivation, understanding of diabetes, and compliance with diet and medications. In terms of knowledge, Brown et al. (2002) found that physicians may not provide current evidence-based guidelines, and are less certain about how to properly administer insulin therapy,
which indirectly affects diabetes self-management (Brown, et al. 2002). The inability to address psychological issues (Peyrot et al., 2005) and poor communication skills in counseling and shared decision-making (Wens, Vermeire, Royen, Sabbe, & Denekens, 2005) also act as barriers to diabetes care.

This challenge of effectively translating knowledge into practice is seemingly heightened for providers who offer care to minority groups. According to the IOM, evidence has shown that health outcomes are less favorable for minority groups when compared to whites in the United States (Institute of Medicine, 2013). Interestingly, access to health care, socioeconomic status, and age as well as other factors, did not contribute to health care disparities outcomes. The area of cultural competence or lack thereof, has gained recognition over the past decade as a potential contributing factor to the increase in health disparities that continue to persist among minority populations (Institutes of Medicine, 2002). According to Orlandi (1987) research knowledge and strategies can fail to translate at the implementation stage due to a lack of cultural competency at the provider level, regardless of successful dissemination efforts (Orlandi, 1987). For example, the CDC has been quite successful in disseminating the DPP with over 625 organizations involved in this effort, but it is uncertain at this time whether providers delivering the behavioral intervention will succeed at the implementation stage. The CDC is evaluating the implementation process by requiring organizations to document and turn in outcome data. At this stage, it is unknown whether DPP interventions will produce results similar to that of the DPP clinical efficacy trial as well as reach diverse populations who can make use of the program. Cultural competence as well as other factors will most likely affect these intervention outcomes.
Cultural competence is defined by the Academy of Nutrition and Dietetics (AND) as: “The ability to provide health care services that are respectful of and responsive to health beliefs, practices, cultural and linguistic needs of diverse patients in order to bring about positive health outcomes” (American Dietetic Association, 2010). Given the importance of providing culturally relevant dietary recommendations, AND views cultural competence as a necessary component in the practice of dietetics (Fox, 2015). To gain an understanding of how cultural competence plays a role in provider care, numerous studies have evaluated how cultural competency training for providers e.g., physicians and nurse practitioners, impacts provider care. A systematic review conducted by Beach et al. (2005), examined the effectiveness of cultural competence training on health care providers. Beach (2005) included a total of 34 studies in the review and concluded that cultural competence training improves knowledge (e.g. traditional cultural practices), attitudes (e.g., cultural self-efficacy), and skills (e.g., Spanish speaking communication skills and behavioral analysis) of health professionals as well as patient satisfaction. However, at the time of this review only one study assessed patient adherence, which resulted in poor evidence of this measure, and no studies assessed patient outcomes in relation to provider training. Currently, evidence on how cultural competence impacts patient adherence and health outcomes is still limited and it is unclear whether providers with better cultural competency skills are able to produce improved health outcomes compared to providers with lower skill levels.

Few randomized control trials have since examined the effects of cultural competency training on diabetes related health outcomes in the United States (Sequist et al., 2010; Thom, Tirado, Woon, & McBride, 2006). Unfortunately, both of these trials
concluded that cultural competency training does not improve clinical outcomes related to diabetes risk factors. Limitations to these studies may in part explain the complex nature of the multifactorial barriers that must be overcome to achieve positive health outcomes. The issue of limited time, most likely affected the results in the study conducted by Thom et al., where the mean patient-physician interaction time was only 2.2+ to 2.8 visits. Sequist et al. (2010) conducted a longer study (12 months), however cultural competency training was voluntary, organizational and social factors were not assessed, and other health related professionals (nurses, nutritionist and pharmacists) who may have the potential to contribute to diabetes care were excluded from the training. Obtaining feedback from providers regarding training, may be an important component to expanding the methodology of cultural competency especially among physicians’ who have acknowledge resistance to training due to the perceived notion that cultural competence is a “soft science.” It is therefore recommended that training be standardized and evidence-based for greater adoption at the provider level (Betancourt, Green, Carrillo & Park, 2015).

While it is clear that cultural competence provides for a more productive provider-patient interaction by increasing patient satisfaction, training that enhances knowledge alone may not be sufficient to impact health outcomes (Reimann, Talavera, & Salmon, 2004). Reimann et al. (2004) assessed the cultural knowledge, cultural awareness and culturally competent actions of physicians on Mexican Americans patients with diabetes. The study concluded that cultural knowledge and even experience working with Mexican Americans in practice, did not translate into culturally competent care. Cultural awareness - the recognition of cultural factors and awareness of personal biases,
were greater predictors of cultural competence. Cultural awareness was found to be greater in physicians who participated in diverse educational settings, were of Latino ethnicity, possessed bilingual skills, and had cultural knowledge. These finding suggests that cultural knowledge is an important component to providing culturally competent care, however training should also focus on the awareness of cultural biases and preconceptions of the provider, expanding educational diversity in different settings, and the development of language skills needed to communicate effectively (Reimann et al., 2004)

Overall, cultural competency is an important component to providing quality care. Through effective communication, cultural competence has shown to increase patient satisfaction, which in turn builds upon the trust and rapport needed for an effective interaction between the provider and patient. In the field of diabetes, cultural competence is a critical component to effectively motivating individuals to practice evidence based lifestyle and behavioral strategies that have shown to prevent and control the progression of the disease.

**The Diabetes Prevention Program (DPP) T2 Research Studies**

Since the completion of the DDP clinical trial, numerous studies have translated the DPP into a variety of diverse clinical and community settings. Due to the intensive nature of the original DPP clinical efficacy trial, modifications to the program were primarily made to reduce costs, as this is the primary rate-limiting step to effectively implementing the DPP into real-worlds settings (Venditti & Kramer, 2012). To reduce costs and investigate new methodological approaches for dissemination and implementation, many translation studies have reduced the amount of sessions offered
and/or trained paraprofessionals to deliver the intervention. Descriptions of DPP translation studies in clinical and community settings are described below and include basic information on six key components: 1) The number of session provided and whether a maintenance phase was offered 2) the setting where the translation study took place 3) the demographics of the participants (i.e., gender, race, and age) 4) who delivered the intervention (eg, health care workers or paraprofessionals 5) weight loss results and other glucose or CVD risk measures 6) main reasoning for results. Other important factors such as attendance, self-monitoring data, focus group data, and cost data are not discussed in this review; however pertinent data relevant to the current study are referenced in the discussion section.

DPP T2 Research Studies Conducted in Clinical Settings

The primary care setting may provide for an ample environment to implement intensive behavioral lifestyle interventions because it allows for easier access to clinical resources such as patient history, laboratory data, and physician support. In addition, physicians who recommend weight loss to their patients may benefit from the support of health care professionals or paraprofessionals to aid in weight loss. Physicians have reported numerous barriers to successful obesity care, such as, lack of reimbursement, inadequate training in nutrition or counseling, and a need to prioritize medical treatment (Melin, Karlstrom, Berglund, Zamifir, & Rossner, 2005). Translation studies have therefore targeted primary care clinics and community hospital settings to implement and evaluate modified versions of the DPP in these settings.

Lifestyle programs translating the DPP to clinical settings have resulted in clinically significant changes in weight loss and CVD markers in high-risk populations of
similar age, gender and ethnicity (Pagato, Kantor, Bodenlos, Gitkind, & Ma, 2008; Kramer et al., 2009; McTigue, Conroy, Bigi, Murphy & McNeil, 2009; Whittermore et al., 2009; McBride et al., 2008, Wadden et al., 2011). However, differences in DPP protocol modifications such as changes in the length of core sessions (Phase 1) and the maintenance phase (Phase 2) as well as differences in recruited samples (prediabetics versus type 2 diabetics) may in part explain the differences in magnitude of weight loss and CVD markers achieved in these studies.

Pagato et al. (2008) implemented a 16-week group-based intervention with monthly “alumni” groups (maintenance phase) in a hospital-based weight loss clinic. Participants (n=155) were primarily overweight Caucasian (90.7%) females (72%), with a mean age of 48.8 years. Trained health care professionals i.e., dietitian, exercise physiologist, and psychologist, delivered the intervention. After 16 weeks, mean weight loss was 5.57 kg (SD 4.55) in the whole subject sample and 6.5 kg in participants without comorbidities. The intervention resulted in 49% of participants losing 5% of initial weight, and 30% reaching the 7% weight loss goal. Pagato et al. compared these findings to the original DPP study and found that the mean weight change in the original DPP (M= - 6.5kg, SD = 4.7) was significantly greater in comparison (M= - 4.57, SD = 4.55) (p <.05). Furthermore, the percentage of weight loss in the DPP (M=6.9%, SD = 4.5) was also significantly greater (4.5%, SD = 3.5) (p <.05), and a significantly higher percentage of DPP participants (49%) reached the 7% weight loss goal compared to participants in Pagato’s study (30%) (p <.05). Potential reasons for not meeting the DPP weight loss goal was possibly due to the higher percentage of participants with comorbidities i.e., depression (35%), binge eating disorder (30%) and Type 2 diabetes (21%), compared to
DPP participants. Participants who did not have comorbidities had a higher percentage of weight loss (40%) that was comparable to that of the DPP (49%).

Kramer et al. (2009) implemented the 12-session Group Lifestyle Balance (GLB) intervention into six primary care clinical practices (four sites in Phase 1 and two sites in Phase 2) and offered bi-monthly maintenance support for one year from the Diabetes Prevention Support Center via telephone and e-mail (eight contacts). In both phases combined, participants were primarily overweight white (85%) women (80.5%) with a mean age of 55.1 years (n=93). Trained health care professionals which consisted of nurses, exercise physiologists, a health educator and a dietitian, facilitated the intervention. After the 12 week program, the average combined mean weight loss for both groups was 7.4lbs (3.36kg), which resulted in a 3.5% total weight loss (P<0.001). A total of 52.2% and 23.8% of those who completed the program met the 5% and 7% weight loss goal. For those who continued into Phase 2 (n=44), more than 80% of these participants’ met the 7% weight loss goal were able to maintain this weight loss at six months. A significant decrease in glucose was found in the Phase 1 at three month (-4.63mg/dL, 3.7%, p=0.02), however this change was not found in the Phase 2 where the average weight loss was higher (-9.9lbs, -4.9%, p<0.001) over time (at 12 months) compared to the Phase 1 (-4.6lbs, -2.2%, p<0.001) at 3 months. Participants who completed Phase 2, however had significant decreases in total cholesterol (-14.9mg/dL), non-HDL cholesterol (-8.6mmHg), systolic blood pressure (-8.6mmHg) and diastolic blood pressure (-3.1 mmHg), whereas these changes were not seen in the Phase 1. It may be expected that greater weight loss would result in lower glucose levels however, evidence suggests that weight loss alone may not be sufficient to improve glycemic
control (Manning, Jung, Leese, & Newton, 1998). Another DPP translational study, which resulted in unexpected changes in HgA1C, found that weight loss was not associated with glycemic control, but improvements in the diabetes self-management (Mayer-Davis, 2004)

In a randomized control study conducted by McTigue et al. (2009) changes in weight loss were similar to that of Kramer et al. 2009. Like Kramer (2009), McTigue et al. (2009) implemented the 12-session group-based version of the DPP (GLB) into a clinical practice setting, involving subjects (n=155) of similar age (mean age of 49.91) and gender (84% female). Race was not reported. The Phase 2 portion of the study differed from Kramer in that sessions were offered in person rather via email or phone. A nurse educator delivered the program and several physicians and a clinical administrator met on a regular basis to discuss program development and progress. At one year, after phase 1 and 2 of the study, mean weight loss was 5.2 kg in the intervention group and + 0.2 kg weight increase in the control group (p<.001). Twenty-seven percent of the intervention group and 6% of the control group achieved the 7% weight loss at one year. Multiple limitations were reported in this study, however there was a lack of follow-up data on patients who planned on moving or changing medical practices, so changes in weight loss may have differed if this data was available to analyze.

Of the four studies that were translated to primary care settings or community hospital settings, Whittemore et al. (2009) reported the lowest percentage of weight change. This study randomized patients from four different primary care settings to an enhanced care program (n=27) or a DPP based lifestyle change program (n=31). This lifestyle program differed from other adapted DPP protocols in that 6 in-person
individual sessions were offered and 5 phone sessions were offered (11 contacts), but like the original DPP, was implemented over a 24-month period. The intervention was delivered by trained nurse practitioners, however the study nutritionists’ who were blinded to the site assignment provided counseling on nutrition related material. This intervention in weight loss after implementing an 11-session DPP intervention conducted at 4 different primary care settings. The subjects (n=58) were also primarily overweight females (92%) with a mean age of 48.2 ± 12.4 years, however were of mixed race (45% White; 34% AA; 21% Hispanic). At 6-months, 25% of intervention participants reached the 5% weight loss goal compared to 11% of the standard care participants, however mean weight loss was not reported. Whittemore et al. (2009) also measured and found decreasing trends in insulin at 120 minutes (p=.001) and greater increases in exercise rates (p=.01) in subjects with a 5% or greater weight loss. In addition, participants who had a higher percentage of weight loss (p=0.8) in the lifestyle program showed trends towards higher HDL levels (p=.21). Lower percent changes in weight may be in part due to the effectiveness of the 5 phone sessions offered. It was reported that phone sessions were difficult to complete and rescheduling of these appointments were often lost to follow-up and therefore, hindered the effectiveness of the program that was intended for patients enrolled in the study.

**DPP T2 Research in Clinical Settings Using Paraprofessionals**

Considering 54% of costs ($750.00 out of $1399.00) in the original DPP lifestyle group (first year alone) were associated with individual counseling services delivered by behavioral experts e.g., psychologists and registered dietitians. Wadden, et al. (2011) utilized medical assistants’ (MA’s) to deliver a modified “brief” version of the DPP. This
study was a two-year randomized control trial in a large network of primary care practices, which included six study sites and involved 31 primary care physicians. The study involved three intervention groups (usual care, brief lifestyle counseling (Brief LC), and enhanced lifestyle counseling (Enhanced LC). The usual care intervention received quarterly PCP visits (2 per year), and the Brief LC and Enhanced LC lifestyle counseling received usual care treatment plus eight additional lifestyle counseling sessions (10- to 15- minute). The Enhanced LC also received their choice of weight-loss medications (orlistat or sibutramine) or two dietary (plus one snack meal) replacements per day (Slim-Fast shakes or Unilever bars) were offered to patients. Participants (n=390) were primarily overweight white (59.0%) women (79.7%) with a mean age of 51.5±11.5 years. A total of 38.5% of participants identified themselves as black and 4.6% as Hispanic. This study differed from other translation studies in that the counseling sessions were delivered by medical assistants (MA’s) who had eight hours of direct training from study staff and met with PCPs on a quarterly basis for guidance. At month 24, the mean (±SE) weight loss for the Enhanced LC group was significantly greater (4.6±0.7 kg; p<0.003) than the usual care group (1.7±0.7kg), however other between-group differences were not significant. Participants in the Enhanced LC group lost an average of 4.7% of their initial weight at 24 months. At one year at 47% of these participants reached the 5% weight loss goals, but this percentage dropped to 35% at 24 months. The Brief LC group lost an average of 3.5% at one year, but did not reach the 5% weight loss goal at 24 months. Based on pilot study data, a greater percent weight loss was expected for the Brief LC group and may have been related to significantly lower attendance compared the Enhanced LC group. The authors do propose that the use
of specialized personnel (e.g., registered dietitians) and more sessions for the first three months may have resulted in greater weight loss. Nonetheless, the design and protocol used in this study offers a unique obesity treatment model for the primary care setting. This was the first model that utilized MA’s to deliver a modified “brief” version of the DPP and offer alternative weight loss methods (medications and meal replacements).

**DPP T2 Research through the Use of Internet Technology**

The use of internet technology for disseminating and implementing the DPP has been explored as an alternative option to individual or group contact interventions. This form of delivery has the potential to improve access and adherence for individuals who may have scheduling conflicts or find it more convenient to attend online sessions rather than in person sessions (Vendetti & Kramer, 2012). Recent DPP adapted translation studies have used DVD (Kramer, Kriska, & Venditti, 2010), telehealth (Vadheim et al., 2010), and internet based programs (McTigue et al., 2009) to assess efficacy.

Kramer et al. (2010) implemented the 12-session GLB program into primary care clinics. A maintenance phase (phase 2) was not implemented during this study. Recruited participants were given the option to enroll in the GLB program delivered via DVD (GLB-DVD) (n=22) or the group-based in person program (GLB-GROUP) (n=26). Of the 48 individuals who enrolled, the majority of participants were Caucasian (83%) females (70.8%), with a mean age of 59.7 years. The program was delivered by trained health care providers. GLB-DVD participants received a total of 12 weekly contacts from the health care professionals via telephone and DPP sessions were viewed one time per week for 12 weeks via DVD. At three months, the overall mean percent weight loss was higher in the GLB-GROUP (6.6%) compared to the GLB-DVD (5.6%). When analyzed
individually, the GLB-GROUP (n=17) and GLB-DVD (n=10) each had the same percentage of participants (71%) that reached the 7% weight loss goal.

In collaboration with the Montana Department of Health and Human Services (DHHS), Vadheim et al. (2010) administered a 16-session modified version of the DPP and 6 monthly after core sessions in a community based health care center. The intervention was recorded on-site and offered via telehealth simultaneously to two separate groups. Two to 4 weekly physical activity sessions were also offered to the onsite group. Participants in both the onsite group (n=13) and telehealth group (n=14) were primarily female (93%) and (69%), with a mean age of 50 and 53 years. Race was not reported. A dietitian and a certified diabetes educator (lifestyle coaches) delivered the program. At the end of 16 weeks, the onsite group and telehealth group had a similar mean percent weight loss of 46% and 50% respectively. There were no statistically Significant differences in dietary fat intake, physical activity and attendance between the two groups, which may indicate that telehealth may provide for a successful alternative method to delivering the DPP.

An alternative method to delivering the DPP online via the internet have been explored by McTigue et al. (2009), however in terms of weight loss this method did not demonstrate the degree of efficacy when compared to Kramer et al. (2011) and Vadheim et al. (2010). This study resulted in 30% of internet participant reaching the 5% weight loss goal and 18% reaching the 7% weight loss goal. Although these results are fairly good, the use of the internet method may be suitable for highly motivated individuals.
DPP T2 Research Targeting Minority Groups in Clinical Settings

In the clinical setting, recruited samples in DPP translation studies have been overrepresented by white, middle aged, female participants. Studies targeting minority groups in clinical settings are limited and recruitment samples tend to be African American individuals diagnosed with type 2 diabetes rather than prediabetes (Cramer, Sibley, Bartlett, Kahn, & Loffredo, 2010; Mayer-Davis, 2004). Changes in weight loss however, did not reach clinically significant reductions of at least 5-7% in these studies. Cramer et al. (2010) implemented a 7-session individualized intervention (one time per month with phone calls two times per week) in family medicine clinics located in the inner-city of Buffalo, New York, which was delivered by nurse case managers. A maintenance phase was not implemented in this study. Participants (n=67) were randomized to an intervention group or usual care group. Demographic data was not available, however participants were predominantly African American and all were diagnosed with type 2 diabetes. At 8 months, weight decreased in the intervention group by -2.47 kg (2.49%) and increased in the usual care group by +0.88 kg (P=.011). Furthermore, the intervention group had significantly lower HgbA1C levels (-1.87 ± 0.81) compared to the usual-care group (-0.54 ± 0.55) (P=.011), which suggests that utilizing a combination of usual care medical management in conjunction with ongoing disease management monitored by case managers, has a greater effect on critical diabetes outcomes compared to usual care.

Despite conducting a longer intervention, Mayer-Davis (2004) reported similar changes in weight loss after implementing an individualized 16-week modified DPP curriculum with maintenance contacts for 6 months into two health care centers.
Participants (n=152) were predominantly African American (82.0%) women (80%) with a mean age of 59.7 ± 8.6 years. Participants were randomized to an intensive lifestyle intervention, reimbursable lifestyle intervention, or usual care. At 6 months, the intensive-lifestyle group had a greater mean weight loss (5.72 lbs/2.6 kg) compared to the usual-care participants (0.88 lbs/0.4 kg) (p<.01) however, changes in HbA1c were not significantly different between the intensive (-1.6) and usual care (-1.1) groups. None of the participants met the 5% weight loss goal. Although, a greater reduction in weight loss was expected in a longer intervention where more DPP sessions are offered, these findings may suggest that weight loss is more difficult to achieve in an elderly individuals with type 2 diabetes. Furthermore, dietary and exercise behavioral habits, which have been shaped throughout life, may be more difficult to change as the duration of type 2 diabetes progresses.

In conclusion, it is difficult to determine the primary determinants that affect the magnitude of weight loss and critical diabetes measures in studies conducted in clinical settings, it is clear that DPP lifestyle interventions produce greater changes in critical diabetes related outcomes compared to standard or usual care alone. Overall, weight loss was the greatest in the high-risk older adult population (Pagato et al., 2008; McTigue et al., 2009; Whittemore et al., 2009) compared to the exclusively type 2 diabetic population (Cramer et al., 2010, Mayer-Davis, 2004). Numerous factors seems to play a role in these outcomes and include, but are not limited to cost restraints, duration of the intervention, number of DPP sessions implemented, participant demographics, changes in dietary and exercise habits, and training and skills of the facilitator. These factors should be considered when comparing differences in diabetes related outcomes in clinical settings.
Whether these interventions are sufficient to prevent or delay the onset of diabetes, or help manage type 2 diabetes related complications remains unclear. Additional research is needed in this area where longer interventions track and measure incidences of type 2 diabetes.

**DPP T2 Studies Conducted in Community Settings**

Interventions offered in community settings provide the opportunity to target and reach specific populations groups that can benefit from evidence-based interventions. Community-level interventions often differ from clinical-level interventions in that they are broader based rather than individual based, and if implemented effectively have the ability to influence behavior change through social support networks (Ockene, 2014). For example, a DPP translation study (the DEPLOY study) conducted by Ackerman et al. (2008) found that a modified version of the DPP implemented into YMCA’s by trained employees, was efficacious as well as cost effective. Based on these research findings, this particular implementation protocol is currently being modeled and offered in YMCA’s across the nation. However, despite the demonstrated efficacy of the DEPLOY translation study, the recruitment sample in this research study was not diverse and consisted of primarily Caucasian participants (93%), which has been a common theme in this area of research.

Compared to the clinical setting, recruitment samples in DPP community translation studies are much more diverse, however the majority of participants still tend to be predominately Caucasian, and implementation testing of the DPP into diverse populations is surprisingly limited. For example, numerous community-based DPP translation studies have primarily focused on older adult Caucasian populations.
Alda et al., 2006; Barham et al., 2010; Katula et al., 2011; Ackerman et al., 2008; Seidel et al., 2008; Barham et al., 2010; West et al. 2011). The majority of these studies have shown promise in reducing clinically significant weight loss as well as CVD risk factors associated with type 2 (Katula et al., 2011; Ackerman et al., 2008; Barham et al., 2010; Seidel et al., 2008; Aldana et al., 2006). Fewer DPP interventions have focused on older adult African American populations (Davis-Smith et al., 2007; Boltri et al., 2008; Dondani & Fields, 2010), and only two studies have targeted the Native American population (Jiang et al., 2013; Admundson et al., 2009). Jaber et al. (2011) was the first and only study to target Arab Americans, and Mau et al. (2010) was the first to target a Native Hawaiian and Pacific Islander community.

Considering the Hispanic population is the fastest growing minority group in the U.S., diabetes prevention efforts based on the DPP lifestyle intervention has been extremely limited. Currently, there are only three DPP translation studies that have solely targeted Hispanic or Latino communities (Ockene et al., 2009; Ruggiero et al., 2011; Vincent et al. 2014) and one study that targeted both an African American and Hispanic community (Parikh et al., 2010). The importance of implementing and evaluating the effects of behavioral lifestyle interventions within Hispanic communities is critical in diabetes prevention. So far, studies that have solely targeted Hispanic or Latino minority groups have resulted in less efficacious interventions compared to studies that have targeted primarily Caucasian groups. Identifying barriers, such as the attitudes and belief systems that may hinder the behavioral lifestyle changes necessary for diabetes prevention is an important factor in providing adequate care to individual and groups suffering from health disparities. Brief descriptions of DPP translation studies that have
solely targeted Hispanic groups are presented below (Ockene et al., 2009; Ruggiero et al. 2011; Vincent et al., 2014). Table 3 presents the DPP translation studies, which have solely targeted Hispanic or Latino groups, and displays the number of curriculum sessions (contacts) and weight loss for each of these studies in comparison to the original DPP clinical trial.

**DPP T2 Research Targeting Hispanic or Latino Groups in Community Settings**

Ruggiero, Castillo, Quinn, & Hochwert (2012) implemented a 16-week group-based culturally sensitive intervention followed by 6 monthly maintenance sessions in multiple community settings (e.g. public schools and family service centers). Participants (n=69) were primarily overweight Hispanic (100%) females (92.8%), with a mean age of 37.86 years. Trained community health workers (CHW) that were members of the community delivered the intervention. After 16 weeks, mean weight loss reached 4.82lbs. (P<.05), however at 12 months weight increased 2.03lbs and did not remain significantly different. In addition, weight circumference and body fat significantly decreased at 6 months (P<.05), however these measures did not remain significant at 12 months. At 12 months, 30% of participants achieved the 5% weight loss goal and 16% achieved the 7% weight loss goal. These finding are consistent with the literature supporting the challenges of maintaining long-term weight loss (Venditti & Kramer, 2012). This study found that physical activity levels decreased and dietary fat intake increased after the intensity of the intervention decreased from 16 per week to once per month. These finding suggest that alternative strategies are needed to consistently maintain dietary and physical activity lifestyle modifications.
Ockene et al., 2012, implemented a literacy sensitive and culturally tailored intervention in multiple community centers (e.g., family health centers and a YMCA). A total of 16 sessions (3 individual and 13 group sessions) were offered over a 12-month period. Participants (n=312) were primarily overweight Spanish speaking Latino (60% Dominican origin and 40% Puerto Rican) females (74.4%) with a mean age of 52 years. Participants were randomized to a lifestyle intervention (LI) or usual care (UC) group. The intervention was delivered by trained community individuals. At one year, participants in LI intervention achieved a modest, but significant weight loss of 2.5lbs vs 0.63lbs (P=.004). Despite the modest weight loss in the LI intervention group, significant changes in HbA1c and insulin resistance were correlated with weight loss (p<.001). These findings may suggest that only modest weight loss is needed to improve HgA1c and HOMA-IR in Caribbean Latinos compared to other populations.

Vincent, McEwen, Hepworth, & Stump (2014), implemented a culturally tailored five month program with 8 weekly sessions and 3 monthly maintenance sessions into multiple community churches settings. Participants (n=58) were primarily overweight Spanish speaking Hispanics (100% Mexican decent) females (77.6%) with a mean age of 50.9 years. Participants were randomized to an EVS intervention group or control group. The intervention was delivered by a bilingual promotora. At 5 months, participants in the intervention group had significant reductions in weight, waist circumference, and BMI compared to the control group. A significant improvement in the diet self-efficacy score was also found in the intervention group. Intervention participants achieved mean weight loss of 6.2lbs, which resulted in a 3% reduction in body weight from baseline. The
authors suggest that a longer study intervention for this population was mostly likely needed to achieve a clinically significant weight loss of 5% to 7%.

Table 3

*DPP T2 Studies Targeting Hispanic or Latino Groups in Community Settings*

<table>
<thead>
<tr>
<th>Study setting &amp; provider</th>
<th>Lifestyle N (only)</th>
<th>Contacts provided (0-6 mo)</th>
<th>Contacts provided (7-12 mo)</th>
<th>Mean weight loss, lbs</th>
<th>Mean weight loss, %</th>
<th>Reach &gt; 5% loss</th>
<th>Reach &gt; 7% loss</th>
<th>Mean BMI, kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowler et al. (2002) HCP</td>
<td>1079</td>
<td>16+PA session 2 x per week</td>
<td>~8 (4 phone, 4 in person)</td>
<td>14.52lbs</td>
<td>7.0</td>
<td>50%</td>
<td>NR</td>
<td>33.9</td>
</tr>
<tr>
<td>Ockene al. (2012) Community individuals</td>
<td>312</td>
<td>16 total x 12 mo *Unknown how the sessions were dispersed</td>
<td>16 total x 12 mo</td>
<td>2.5lbs (12 mo)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>33.9</td>
</tr>
<tr>
<td>Ruggiero et al., (2010) CHW</td>
<td>69</td>
<td>16</td>
<td>6 monthly</td>
<td>4.82lbs. (6mo) &amp; 2.03lb (12mo)</td>
<td>NR</td>
<td>30% at 12 mo</td>
<td>16% at 12 mo</td>
<td>31.19</td>
</tr>
<tr>
<td>Vincent et al. (2014). Promotora</td>
<td>58</td>
<td>8 weekly 3 monthly x 5mo</td>
<td>None</td>
<td>6.2lbs. (5mo)</td>
<td>3.0</td>
<td></td>
<td></td>
<td>34.32</td>
</tr>
</tbody>
</table>

NR=Not reported
CHAPTER III

METHODS

Research Study Design

Residents from two separate TELACU assisted living facilities (Manor and CASA) located in Los Angeles County (Los Angeles, CA) were eligible to participate in the diabetes prevention and management study. The intervention was an eight-week (1 time a week) group-based culturally sensitive education program, which included a 4-week non-intervention period. The curriculum chosen for the study was primarily adapted from the original DPP, National Diabetes Education Program curriculum (Diabetes Prevention Research Group, 1996), and also incorporated nutritional teaching tools that meet the American Diabetes Association National Standards for diabetes self-management (Funnell, 2009; Funnell et al., 2007). Prior to implementing the intervention, the study facilitator reviewed the DPP manual of operations procedures and DPP curriculum, which are available online for public use (http://www.bsc.gwu.edu/dpp/manuals.htmlvdoc). While the design of the DPP lifestyle intervention utilized different behavioral principles, the theoretical education model for this study was derived from the Social Cognitive Theory and specifically involved integrating SCT determinants to assist in behavioral change (Bandura, 1997). Out of the 16 core-curriculum DPP sessions available, eight sessions were chosen for the intervention. The post-core curriculum sessions were not conducted in this study. Due to the inclusion of participants at risk for diabetes and with type 2 diabetes, the DPP was modified to meet the needs of both these study populations. Therefore, the education program focused on improving dietary and physical activity lifestyle behaviors and
emphasized preventing diabetes as well as diabetes related complications. The specifics of the lesson plan developments and DPP modifications are presented under the, “Lesson Plan Development” sub-section. Outcome measures were performed four times throughout the study and included monitoring changes for the following assessments: weight (lb), BMI (kg/m\(^2\)), percent body fat, fasting capillary blood glucose, and self-report physical activity. The program started in February 2011 and ended in May 2011. After the completion of the diabetes study, a focus group intervention was conducted during the last week of June 2011. The focus group findings were used to assess the study curriculum and evaluate the effectiveness of the diabetes prevention and management study.

**Participant Screening and Eligibility**

Residents at each of the two TELACU facilities were invited to onsite presentations describing the study goals and objectives. The presentations were held in the communal living area where the residents lived. The presentations were given by a registered dietitian (student investigator and facilitator) and translated to Spanish by two different Social Service Coordinators (SSC’s) managing the separate TELACU living facilities. Individuals who were interested in participating in the study were invited to complete initial screening questionnaires and baseline assessments. Prior to conducting initial screenings and baseline assessments, all participants gave written informed consent.

The screening and baseline assessment objectives were to recruit overweight (BMI of ≥ 25 kg/m\(^2\)) elderly Hispanic individuals (≥ 60 years of age) with elevated fasting capillary blood glucose (≥ 100mg/dL-125mg/dL), and those already diagnosed
with type 2 diabetes ($\geq 126$ mg/dL) (3). Individuals who were overweight (BMI of $\geq 25$ kg/m$^2$) and without a prior diagnosis of pre-diabetes or type 2 diabetes were also eligible to participate. TELACU residents who did not meet the inclusion criteria were allowed to attend class sessions and complete outcome measures, but were not included in the final data analysis. TELACU management encourages all residents to participate in programs offered at their facilities and therefore, were not denied involvement in all study classes and measurements. Participants were excluded from the final data analysis if they had renal disease; had impaired mental status such as Alzheimer’s disease; had a drug or alcohol abuse problem, had unstable angina, had an eating disorder, had liver disease or cancer, had verbalized no interest in weight loss; had a BMI of $\leq 24$ kg/m$^2$; were $< 60$ years old, had contraindications to participating in physical activity, and did not attend at least five of the eight sessions offered. Given that elderly individuals with type 2 diabetes often suffer from diabetic related health complications, those diagnosed with neuropathy or cardiovascular diseases were included in the final data analysis.

A total of 37 TELACU residents were interested in participating in the study. To assess eligibility, all residents completed a series of questionnaires. To determine age and diabetes status, residents completed a pre-screening questionnaire developed by the investigators. In addition, a health history questionnaire was administered to further assess general health and medication use. These questionnaires revealed that all residents interested in joining the study were greater than 60 years of age and the majority of residents (29 of 37) were previously diagnosed with type 2 diabetes. A total of eight residents indicated they had never been diagnosed with higher than normal blood sugar or
pre-diabetes. In terms of general health status, one resident reported a hepatitis C diagnosis, one reported hemophilia, and another was currently being treated for end stage renal disease. While these three residents were allowed to join class sessions, they were not included in the final data analysis.

To assess place of origin, race and ethnicity, a demographics questionnaire was also administered. All residents reported they were of Hispanic, Latino, or Spanish origin and further specified they were of Mexican, Mexican American, and/or Chicano origin. Upon distributing the demographics questionnaires, the language preference for each resident was recorded by the study facilitator.

To further screen and gather baseline measurements, height (in), weight (lbs), body mass index (kg/m\(^2\)) and fasting capillary blood glucose (mg/dl) were measured. These measurements indicated that all residents had BMI levels greater than 24 kg/m\(^2\) and a total of four residents had fasting capillary blood glucose levels between the ranges of 100mg/dL-125mg/dL. For study purposes, these four individuals were classified as meeting the American Diabetes Association diagnostic criteria for prediabetes (American Diabetes Association Standards of Care, 2011), however each of these residents were asked to follow-up with their doctors for further diagnostic testing regarding possible prediabetes.

To determine contraindications to physical activity (PA), residents completed a Physical Activity Readiness Questionnaire (PARQ). Two residents reported chest pain while engaging in PA. These participants were informed not to participate in the exercise portion of the study and report these symptoms to their doctors. These participants were allowed to join the nutrition portion of class sessions, but were denied involvement in
physical activity demonstrations. Of the 37 residents interested in joining the study, 32 met the eligibility criteria. As mentioned above, three residents were not eligible due to medical health issues and two individuals had contraindications to PA. Participant characteristics for the final sample are presented under the results section in Table 10.

Measures

Anthropometric Measurements

Height (in) and weight (lb) measurements were performed by the study facilitator who was trained in conducting these measures in both the clinical and community setting. Height (in) was measured once at baseline using a wall mounted measuring tape and weight (lb) was measured four times throughout the study using a calibrated Tanita Bioelectrical Impedance Analysis (TBF 300) scale. Participants were asked to remove shoes, hats and heavy clothing before each measure. To ensure accuracy, body weight measures were conducted two times for each participant. At each weight measure, height (in) was manually inputted into the Tanita scale handheld device and each participant was asked to step on the center of the scale. Weight measures that were inconsistent were conducted until accuracy was achieved. Body mass index (BMI) and percent body fat (%BF) were automatically calculated and printed via the Tanita BIA scale. Participants were provided with one copy of their results and the second copy was attached to the participants tracking sheet. Participants were encouraged to keep track of their weight measures throughout the entire study.

Fasting Capillary Blood Glucose

Fasting capillary blood glucose samples were obtained by a registered nurse (RN) who was trained in conducting these measures in a clinical setting. Blood samples were
taken with a calibrated glucometer monitoring device (Abbott FreeStyle ® Lite Blood Glucose Meter) using new compatible test strips (Abbott FreeStyle ® Lite Test Strips). The Abbot FreeStyle ® Lite glucometer measures fresh capillary whole blood samples and has a 10% ± valid comparison to a reference value if taken 10 minutes apart (Abbot Diabetes Care, 2011). Capillary whole blood samples are estimated to be approximately 10-15% lower when compared to plasma (venous) blood glucose samples (Cengiz & Tamborlane, 2009), and therefore, all participants were informed that glucose test results taken for the study may differ from the laboratory results received from their doctors. All capillary blood samples were taken between the hours of 8:00 and 9:15 A.M. following a 12-hour overnight fast. A day before the blood draws, participants were asked to abstain from moderate to heavy exercise for at least 24 hours, maintain adequate hydration and consume three normal meals prior to their fast. Universal sanitary precautions for blood handling were conducted using the following procedures: 1) Putting on and changing gloves prior to and after each test; 2) cleaning the index finger with an alcohol pad; 3) sticking the index finger with a non-reusable lancet (Owen Mumford AT 1042 Unistik 3 Comfort Safety Lancets, 1.8mm Depth, 28 Gauge); 4) placing a drop of whole blood on a test strip; 5) discarding the lancet, test strip and gloves in a Sharps container immediately following each blood test. The Sharps container was collected by the registered nurse and disposed of at a biohazard pick up site located in Los Angeles County (Glendora, CA).

**Women’s Health Initiative Physical Activity Questionnaire**

The Women’s Health Initiative Physical Activity Questionnaire (WHI PAQ) was used to assess changes in the participants’ physical activity levels from baseline (week 0)
to the end of the intervention (week 12). The WHI PAQ questionnaire evaluates physical activities such as recreational walking as well as household and yard activities. While this questionnaire was designed for the Women’s Health Initiative (WHI) Study, it has shown to be a reliable assessment for recreational walking, which was of particular interest for this study (Meyer et al., 2009). Participants reported on the usual frequency, duration, and pace of recreational walking (questions 1-1.2) and the intensity (strenuous, moderate, or mild) of recreational activities (questions 2-4.1). Since the minimum PA goal of this study was to engage in at least 30 minutes of walking per day, household and yard activities were not assessed. Changes in physical activity were monitored by the study facilitator throughout the intervention and were used as a tool to encourage physical activity participation.

**Qualitative Ratings Questionnaires & Oral Informative Evaluations**

To ensure a need-based and culturally sensitive intervention, participants completed written ratings questionnaires after each educational session. The study facilitator developed the questionnaires weekly after the completion of each lesson plan. A rating forms format was used to determine which lesson plan topics participants found most useful and how each topic ranked among the others. The questionnaires also asked participants to list any new or prior class topics that they would like to learn more about. After each session, the facilitator reviewed the evaluations, and participant feedback was used to modify lesson plans on a weekly basis. In addition, oral informative evaluations were conducted midway and at the end of each intervention session. Informative evaluations prompted the facilitator to clarify and address participants’ needs and questions during class sessions.
Attendance

The number of participants attending each class was recorded by the study facilitator. At the start of each session participants were given a sign in sheet and asked to sign their names on the form. After each session, the facilitator documented the attendance compliance for each participant. Attrition rates were used to determine which participants met the study completion criteria. Participants who attended at least five of the eight sessions were included in the final data analysis.

Data Collection Procedures for All Measures

All outcome measures were conducted at week 0 (baseline), 4, 8, and 12 weeks. Week 8-12 was a 4-week non-intervention period. Eligibility screening was conducted only at baseline (week 0). The qualitative ratings questionnaires, oral informative evaluations and attendance recordings were gathered at each of the educational sessions. All assessments were conducted at the TELACU living facilities in the communal living area where the participants lived. Prior to each data collection, participants were provided with a handout indicating the date and time of each assessment as well as instructions for fasting blood glucose testing. All study measures were conducted on Monday mornings at each facility between 8-9:15AM. At the screening and baseline testing (week 0), participants met with the study facilitator and Social Service Coordinators who informed participants about the study protocol. Participants were then provided with a written consent form approved by the California State Polytechnic Pomona University Institutional Review Board. Each participant was asked to read and sign the form prior to completing the screening and study measures. After providing written consent, participants then completed the pre-screening form, health history questionnaire,
demographics questionnaire, PARQ and the WHI PA questionnaire. The Social Service Coordinators assisted individuals who had difficulty filling out questionnaires and answered any questions participants had about the study protocol. As participants completed their questionnaires, they met with the study facilitator who conducted their height and weight measurements. After anthropometric testing was completed, participants met with the registered nurse who then conducted fasting capillary blood glucose measurements for each participant. The same procedures were followed for the week 4, 8, and 12 measurements. Participants who were not able to attend the scheduled study measures, were given an opportunity to meet with the study facilitator the following day to conduct weight measures, however the study nurse was not available for re-scheduling and therefore, blood glucose measures were not conducted on these alternate days. After participants completed all study measures, they were provided with an appointment slip indicating the start date and time of each educational session.

**Statistical Analysis**

The primary dependent variables were weight (lbs), fasting plasma glucose (mg/dL) and percent body fat (%BF) measured before the educational intervention (Week 0) and at weeks 4, 8, and 12 after the implementation of the educational program. Secondary dependent variables were height (in), body mass index (BMI), self-reported physical activity levels, and qualitative ratings of the lessons. Body mass index was calculated from height and weight. There was no need to statistically analyze BMI because the information it contains is redundant with weight. It can be presumed that participants’ height will not change significantly across the study period. Hence, any changes in BMI will be due to changes in weight.
This study needed a minimum number of 24 subjects to utilize a parametric test such as ANOVA. Due to missing values at week 0 (baseline), 4, 8, and 12, a pair-wise post-hoc using Tukey Honestly Significant Difference (HSD) could not be used to assess inequities among the means over time. Data are presented descriptively as mean ± SD for week 0 (baseline), 4, 8, and 12. Sufficient data for weight/BMI and percent body fat was available at week 0 (baseline) and week 12 and was assessed using a paired-samples t test with a P < 0.05 set for statistical significance. This data was analyzed using SPSS statistical software. Outcome variables (BMI and fasting plasma glucose) measured at baseline, 4th week (BMI only), 8th week, and 12th week were compared to baseline values. Qualitative ratings of the lessons are reported descriptively. The primary purpose of these ratings was formative evaluation – that was, to adjust the educational program in light of feedback from the participants. Attendance data for the educational program (compliance) is also reported descriptively.

**Diabetes Prevention & Management Education**

The diabetes prevention and management education classes were conducted in both English and Spanish once a week during the 2-month study period. Class sessions were conducted at both the Manor and Casa TELACU assisted living facilities in the communal living area where the participants lived. Classes were held at the Manor facility on Mondays and at the CASA facility on Tuesdays. All classes were held in the afternoon at 2:00 P.M. and lasted approximately one hour and 30 minutes. The classes were led by a registered dietitian (student investigator) and translated to Spanish by two different Social Service Coordinators managing each of the living facilities. The facilitator taught eight modified versions of the DPP core-curriculum. The DPP was
chosen as the curriculum and was modified to meet the needs of the study population. The eight DPP sessions chosen for the intervention are summarized in Table 4.

Table 4

Adapted Diabetes Prevention Program Curriculum

<table>
<thead>
<tr>
<th>Session 1:</th>
<th>Welcome to the Lifestyle Balance Program &amp; Be a Fat Detective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 2:</td>
<td>Being Active: A Way of life</td>
</tr>
<tr>
<td>Session 3:</td>
<td>Healthy Eating</td>
</tr>
<tr>
<td>Session 4:</td>
<td>Tip the Calorie Balance</td>
</tr>
<tr>
<td>Session 5:</td>
<td>Three Ways to Eat Less Fat</td>
</tr>
<tr>
<td>Session 6:</td>
<td>Talk Back to Negative</td>
</tr>
<tr>
<td>Session 7:</td>
<td>Four Keys to Healthy Out</td>
</tr>
<tr>
<td>Session 8:</td>
<td>Ways to Stay Motivated</td>
</tr>
</tbody>
</table>

Modifications to the DPP curriculum were based on the need to include additional education material that addressed the needs of elderly Hispanic participants with and without type 2 diabetes, as well as integrating SCT determinants into each of the lesson plans. Oral and written formative evaluations, budget restrictions, and the length of the intervention also influenced the extent to which the DPP was modified. This curriculum maintained the core principals of the DPP lessons plans by emphasizing healthy eating and physical activity for the purpose of weight loss. However, a major modification to the DPP was due to the inclusion of participants with type 2 diabetes (n=7), which required the facilitator to incorporate educational topics that emphasized the importance of blood glucose control. This resulted in removing educational material from the DPP and adding nutritional teaching tools related to blood glucose management. The education materials used for blood glucose management teachings included the following focus areas: 1) diabetes meal planning emphasizing food groups and portion sizes (Ross & Geil, 2007); 2) the plate method concept (Rizor et al., 1998); 3) portion size teachings using the
“Hand Jive” (American Diabetes Association, 1991); 4) a review of blood glucose levels during exercise (Funnel, 2009); 5) and visual displays of abnormal and normal blood glucose levels (Funnel, 2009). While these educational materials were specifically designed for individuals with diabetes, the principles and importance of glucose management were applied to both overweight participants (n=4) and those with elevated capillary fasting glucose (n=4). The blood glucose guidelines taught to participants were referenced from the American Diabetes Association (American Diabetes Association, 2011). Blood glucose ranges recommended at specific meal times are presented in Table 5 and are further classified by diagnosis. Participants were advised to follow their doctors’ recommendations regarding blood glucose control and/or consult their doctors with any questions related to this topic.

Table 5

<table>
<thead>
<tr>
<th>TIME WHEN BLOOD GLUCOSE IS CHECKED</th>
<th>YOUR GOAL</th>
<th>YOUR GOAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em><strong>Recommended</strong></em> blood glucose ranges for people without diabetes or at risk for diabetes.</td>
<td><em><strong>Recommended</strong></em> blood glucose ranges for people with type 2 diabetes.</td>
</tr>
<tr>
<td>Before breakfast (fasting)</td>
<td>&lt; 100</td>
<td>70 – 130</td>
</tr>
<tr>
<td>Two hours after meals</td>
<td>&lt; 140</td>
<td>&lt; 180</td>
</tr>
</tbody>
</table>


A culturally sensitive intervention was necessary due to the inclusion of solely Hispanic participants. For each of the lesson plans, the facilitator included a culturally relevant topic and activity, which often referenced traditional Hispanic foods. These
topics aimed to address nutritional habits common among the Hispanic population and in turn influence healthy lifestyle changes for the purpose of preventing and managing type 2 diabetes.

In terms of meeting SCT determinants, each lesson plan involved the following three critical strategies to assist in behavioral change: 1) Self-efficacy 2) Goal setting 3) Outcome expectancies (Bandura, 1997). Self-efficacy was encouraged through modeling and practicing activities at each session. Since the DPP included detailed goal setting and outcome expectancies, the facilitator tailored these SCT determinants to match the objectives of the modified lesson plans.

The facilitator considered four main components i.e., DPP curriculum, glucose management, culturally sensitive topics, and SCT determinants, when developing each of the lesson plans. Detailed written explanations of the development process for sessions 1-8 are further described under the “Lesson Plan Development” sub-section. Brief descriptions of how these components were integrated into each of the eight sessions are summarized in Table 6 on the following page.
Table 6

*Components Included in the Lesson Plan Development*

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1</td>
<td>Welcome to the Lifestyle Balance Program &amp; Be a Fat Detective</td>
<td>Benefits of glycemic control independent of weight loss.</td>
<td>Learning to read food labels (fat grams) on traditional food items</td>
<td>1. Track fat grams &amp; engage in 30 min of PA 2. Food labeling activity</td>
</tr>
<tr>
<td>Session 2</td>
<td>Being Active: A Way of Life</td>
<td>Effects of PA on BG &amp; How to manage BG during PA</td>
<td>Sugarfree agua de limón &amp; coconut water displayed &amp; sampled in the hydration session</td>
<td>1. Engage in 30 min of PA &amp; practice chair &amp; wall exercises 2. Chair &amp; wall exercise activity</td>
</tr>
<tr>
<td>Session 3</td>
<td>Healthy Eating</td>
<td>How food groups and portion sizes affect BG &amp; How to plan a meal for BG control (The Plate Method)</td>
<td>Carne asada, rice, beans, salsa, and vegetables were served in the plating of a traditional meal activity</td>
<td>1. Practice the plate method, track fat grams &amp; continue daily PA 2. Create your plate &amp; plating a traditional meal activity</td>
</tr>
<tr>
<td>Session 4</td>
<td>Tip The Calorie Balance</td>
<td>How excess calories &amp; fat affect BG and weight.</td>
<td>Traditional food items were used in the bingo game activity</td>
<td>1. Eat fewer calories by eating less fat, tracking fat grams &amp; engaging in 30 min PA 2. Bingo game activity</td>
</tr>
<tr>
<td>Session 5</td>
<td>Three Ways to Eat Less Fat</td>
<td>Effect of sugar intake on BG and insulin levels &amp; BG target ranges during fasting and postprandial</td>
<td>Learning to read food labels (fat and sugar grams) of traditional dessert items</td>
<td>1. Track sugar &amp; fat grams, continue with PA &amp; monitor blood sugar 2. Guess the amount of sugar activity</td>
</tr>
<tr>
<td>Session 6</td>
<td>Talk Back To Negative Thoughts</td>
<td>Benefits of fiber intake for glycemic control</td>
<td>High fiber fruits, vegetables, nuts/seeds, &amp; carbohydrates commonly used in traditional Hispanic cuisine was used in the fiber activity.</td>
<td>1. Track fiber intake and continue with fat tracking, PA, &amp; blood sugar monitoring 2. Talk Back to Negative Thoughts &amp; Guess the amount of fiber activity</td>
</tr>
<tr>
<td>Session 7</td>
<td>Four Keys to Healthy Eating Out</td>
<td>Managing blood sugar and weight when eating out</td>
<td>A cheese chili relleno recipe was modified</td>
<td>1. Choose a low fat menu item at a restaurant &amp; modify a traditional recipe 2. Modify a Traditional Meal Guess the Difference activity</td>
</tr>
<tr>
<td>Session 8</td>
<td>Ways to Stay Motivated</td>
<td>Meal planning and timing for BG control &amp; Modify recipes (fat &amp; sugar for consistent carbohydrate intake)</td>
<td>Traditional Hispanic cuisine recipe items were prepared during a cooking demonstration</td>
<td>1. Practice motivational techniques &amp; modify recipes 2. Ways to Stay Motivated &amp; cooking low-fat traditional foods activities</td>
</tr>
</tbody>
</table>
Lesson Plan Development

To prepare for the intervention, the facilitator reviewed the DPP Lifestyle Change Program Manual of Operations (Wing & Gillis, 1996). This manual provides procedures on how to implement the DPP lifestyle intervention and was originally intended for DPP Case Managers and staff during the NIH Diabetes Prevention Program Research Study. After a full review of the DPP manual of operations, it was determined that weight scales and fat tracking booklets could not be purchased and provided to each participant due to budget restrictions. These changes affected the goals and expectancies part of the study as weights and fat tracking were expected to be conducted daily in the DPP. In this study, participants were encouraged to keep track of their monthly study weight measures as well as weights conducted at doctor office visits throughout the entire study. A DPP fat counter booklet was not available in Spanish and therefore the facilitator purchased a Spanish nutrition macronutrient resource book for each facility (Ulrich, 2004). This reference book was available for checkout in each of the social service coordinators offices. Participants were expected to utilize this resource to aid in fat tracking.

Session 1

Prior to session one, the facilitator reviewed all recorded weights obtained at baseline (week 0) and calculated the five percent weight loss goal and fat gram goal for each participant. The fat gram goal was determined by referencing the DPP Lifestyle Change Program Manual of Operations (Section 5.3, Table 5.1) – DPP Lifestyle Intervention Fat and Calorie Goals (Wing & Gillis, 1996). Table 7 displays the DPP’s recommended fat and calorie goals based on initial starting weights. After the weight loss and fat gram goals were determined, the facilitator transferred all of the participants’
names, starting weights, weight loss goals, and fat gram goals to each of the participants’ individualized session-one welcome handout packets. The facilitator also re-reviewed all PARQ questionnaires that were completed at baseline (week 0).

Table 7

*DPP lifestyle intervention fat and calorie goals*

<table>
<thead>
<tr>
<th>Starting Wt. (lb.)</th>
<th>Fat Goal (g)</th>
<th>Calorie Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>120</td>
<td>33</td>
<td>1200</td>
</tr>
<tr>
<td>125</td>
<td>35</td>
<td>1200</td>
</tr>
<tr>
<td>130</td>
<td>38</td>
<td>1200</td>
</tr>
<tr>
<td>135</td>
<td>40</td>
<td>1200</td>
</tr>
<tr>
<td>140</td>
<td>43</td>
<td>1200</td>
</tr>
<tr>
<td>145</td>
<td>46</td>
<td>1200</td>
</tr>
<tr>
<td>150</td>
<td>49</td>
<td>1200</td>
</tr>
<tr>
<td>155</td>
<td>52</td>
<td>1200</td>
</tr>
<tr>
<td>160</td>
<td>55</td>
<td>1200</td>
</tr>
<tr>
<td>165</td>
<td>58</td>
<td>1200</td>
</tr>
<tr>
<td>170</td>
<td>62</td>
<td>1200</td>
</tr>
<tr>
<td>175</td>
<td>65</td>
<td>1500</td>
</tr>
<tr>
<td>180</td>
<td>68</td>
<td>2000</td>
</tr>
<tr>
<td>185</td>
<td>71</td>
<td>2000</td>
</tr>
<tr>
<td>190</td>
<td>74</td>
<td>2000</td>
</tr>
<tr>
<td>195</td>
<td>77</td>
<td>2000</td>
</tr>
<tr>
<td>200</td>
<td>80</td>
<td>2000</td>
</tr>
<tr>
<td>205</td>
<td>83</td>
<td>2000</td>
</tr>
<tr>
<td>210</td>
<td>86</td>
<td>2000</td>
</tr>
<tr>
<td>215</td>
<td>89</td>
<td>2000</td>
</tr>
</tbody>
</table>

To prepare for a nutrition facts labeling reading activity, the facilitator purchased numerous food items at a local Mexican market. These items included the following: packaged pan dulce, packaged chorizo, canned beans (full fat and low fat), milk (whole and 1%), tortillas (corn and flour), butter, cooking oils (monounsaturated and polyunsaturated), and three types of ground beef (very lean 5%, medium fat 15%, and high fat 30%). The ground beef was used to create a visual display of the differences in fat content between the very lean (5%), medium fat (15%), and high fat (30%) ground beef. A day before session one the facilitator prepared the display utilizing the following methods: 1. Cooking each type of ground beef in a separate skillet 2. Cooling the ground
beef 3. Placing the three different samples into separate labeled Ziplock plastic sandwich bags 4. Placing each of the bags into the refrigerator for 24 hours. The day of session one, the samples were removed from the refrigerator, placed in an ice chest and brought to session one.

**DPP component.** A modified version of the DPP “Be a Fat Detective” and key principles of the, “Welcome to the Lifestyle Balance” were chosen for session one. At the start of the session, participants’ names were called and the facilitator gave each participant their individualized handout packet. The session began with open-ended questions regarding the participants’ thoughts and views on weight loss (Welcome to the Lifestyle Balance Program–Page 1). Weight loss (5%), physical activity goals, and expectations were reviewed (Welcome to the Lifestyle Balance Program–Page 4). An overview on how “fat” intake effects weight was also discussed (Be a Fat Detective–Page 2). To inform participants about their specific “fat gram” goal, participants were asked to look at their handouts and were informed that their individualized fat gram goals were based off their current weight status (Being a Fat Detective–Page 4). The session then segued into a group discussion about, “What kind of foods do you eat that are high in fat?” (Be a Fat Detective – Page 3). Participants were then taught how to look on a nutrition facts label for the fat grams (Be a Fat Detective –Page 7), which was followed by the food label reading activity. A modified version of the DPP “We will work together as a TEAM” (Welcome to the lifestyle intervention Session –Page 6) was also discussed with participants.
**DM component.** A brief background on the benefits of weight loss for preventing and managing diabetes was discussed. The importance of blood sugar management independent of weight loss was also discussed.

**Culturally sensitive component.** Traditional food items and packages were used as examples during the nutrition facts label reading activity. Nutrition facts on each of the food items were printed in both English and Spanish. As described above, examples of food items included the following: packaged pan dulce, packaged chorizo, canned beans (full fat and low fat), milk (whole and 1%), tortillas (corn and flour), butter, cooking oils (monounsaturated and polyunsaturated), and ground beef (very lean 5%, medium fat 15%, and high fat 30%).

**SCT component.** 1) Goals and Expectancies: A modified version of the DPP, “To Do By Next Week” was developed. The weekly goals and expectations of session one were discussed with participants. Participants were asked to read food labels and write down the total amount of fat grams eaten in one or more days. Participants who were not able to find the fat content of a specific food item, were encouraged to check out the tracking book in the social service coordinators office and ask the facilitator to help them at the next meeting. Participants, who passed the PARQ questionnaire, were encouraged to walk a total of 30 minutes on at least five days of the week. 2) Modeling and Practicing: The nutrition facts label reading activity was developed by the facilitator to engage participants in a modeling and practicing activity. During this activity, volunteers were asked to take a food item from a food display set up by the facilitator prior to the start of the session. Participants were encouraged to share with the group how many fat grams their food item contained. The visual display of the fat content in the...
three types of ground beef (very lean 5%, medium fat 15%, and high fat 30%) was shown to participants at this time.

**Session 2**

Prior to session two, the facilitator met with a certified physical trainer (CSCS NSCA-CPT) to determine an exercise program deemed safe for the study participants. The NSCA Healthy learning™ DVD – Practical Exercises for Sedentary Seniors was reviewed (Yoke, 2009), as well as other exercise programs (Cruise, 2009). A series of nine low intensity chair and wall exercises deemed safe for elderly participants were chosen for an exercise demonstration in session two (Cruise, 2009). The exercises focused on strength and flexibility of the abdominals, upper back, buttocks, thighs, biceps, calves, shoulders, triceps and hamstrings.

In preparation of a post-exercise hydration education session, the facilitator prepared a sugarfree agua de limón using proper safety and sanitation procedures. The agua de limón (flavored water) was sweetened with Stevia instead of granulated sugar. ZICO® coconut water was also purchased and used during the hydration educational demonstration.

**DPP component.** A modified version of “Being Active: A Way of Life” was chosen for session two. Participants who selected one or more items on the PARQ were again instructed to obtain clearance by their healthcare professional prior to starting the recommended DPP exercise regime. The session opened with a review of the benefits of exercise (Move Those Muscles-Page 2) and emphasized how to find the time to be more active (Being Active: Away of Life-Page 1). The signs and symptoms of when to stop exercise were also reviewed (Handout: Keep it Safe). The certified physical trainer (CPT)
informed participants about the importance of stretching for the prevention of sore muscles and cramps (Handout: Keep It Safe). The CPT then led participants through the DPP safe and easy stretches (Handout: Keep It Safe).

**DM component.** The positive effects of physical activity on blood sugar were discussed. The importance of blood sugar management during physical activity was emphasized for those participants diagnosed with diabetes. The facilitator reviewed the risks of low blood sugar, signs and symptoms of hypoglycemia during exercise, and medications commonly known to cause hypoglycemia. Participants were instructed on how to treat low blood sugar based on blood sugar values. A total of 15 grams of carbohydrates was recommend for blood sugar values between 50 and 69 mg/dl and a total of 30 grams of carbohydrates was recommended for blood sugar values less than 50 mg/dl (Funnell, 2009). A list of food items and portion sizes containing 15 and 30 grams of carbohydrates were provided to participants. Handouts were adapted and obtained from the American Diabetes Association, *Life with Diabetes*, teaching outlines (Funnell, 2009).

**Culturally sensitive component.** After the exercise session, participants were informed about the importance of hydration before, during and after exercise. Participants were informed that the traditional agua de limón (flavored water) could be sweetened with Stevia instead of granulated sugar. Participants were provided with samples of sugarfree agua de limón, and ½ cup of ZICO® coconut water. Volunteers were asked to share the sugar content of the ZICO® coconut water and were informed that coconut water could be used to treat low blood sugar.
**SCT component.** 1) Goals and Expectancies: A modified version of the DPP, “To Do by Next Week” was developed. The weekly goals and expectations of session two were discussed with participants. Participants were asked to talk to their doctors about physical activity if they answered yes to any of the questions on the PARQ. Participants’ who passed the PARQ assessment, were encouraged to walk 30 at least five days a week and practice the wall and chair exercises taught to them. Participants were expected to write down the type and duration of physical activity they completed for at least three days. Participants were encouraged to exercise with a partner to increase motivation. 2) Modeling and Practicing: During the chair and wall exercise activity, the CPT asked volunteers from the group to demonstrate the exercises. After the demonstration, all group members were invited to partake in each of the exercises.

**Session 3**

Prior to session three, the facilitator reviewed the fat gram goal for each participant. The calorie goals for each participant were then determined by referencing the DPP Lifestyle Change Program Manual of Operations – DPP Lifestyle Intervention Fat and Calorie Goals Setting (Table 7). For example, participants with a 42 gram fat goal were assigned a 1500 daily calorie goal. The calorie amounts were compared to a standardized diabetic sample meal plan, which was used to determine the recommended daily serving sizes in each food group (Ross & Geil, 2009). Table 7 displays the calorie goals and recommended servings in each food group. The recommended daily serving sizes indicated on the sample meal plan below and “The Idaho Plate Method” (Rizor et al., 1998) were used by the facilitator to develop the, “Create Your Plate” handout/activity and “Plating a Traditional Meal” activity. Figure 2 displays a sample
meal plan developed for participants with a fat gram goal of 42 grams. Since the diabetes sample meal plan did not have a 1500 calorie plan, a total of 100 calories was deducted from the 1600 calorie sample meal plan. This was done by reducing the serving sizes of fat from the 1600 calorie meal plan from five to four servings and starches/carbohydrates from seven to six servings. Table 8 displays the sample meal plan based on calorie amounts and number of recommended serving sizes for each food group.

Table 8

Calorie Amounts & Number of Recommended Serving Sizes for Each Food Group

Sample Meal Plan: Pulling the Food Lists Together

The table below shows sample meal plans, by number of servings, for different calorie requirements. Ask your RD, CDE, or healthcare provider which plan may work best for you. Each plan provides about half of its calories from carbohydrates and less than 25% of calories from fat, based on choosing fat-free milk and low-fat meats (Lean Meat Group) and cheeses.

<table>
<thead>
<tr>
<th>Calories per day*</th>
<th>1200</th>
<th>1600</th>
<th>1800</th>
<th>2000</th>
<th>2200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starches</td>
<td>5</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Fruits</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Milk</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Sweets, Desserts, Other Carbohydrates †</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-starchy Vegetables</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Meat &amp; Meat Substitutes</td>
<td>4 oz</td>
<td>6 oz</td>
<td>6 oz</td>
<td>7 oz</td>
<td>8 oz</td>
</tr>
<tr>
<td>Fats</td>
<td>2</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

* The numbers included in the chart are individual servings from each food list.
† Consult with an RD about how to substitute foods from the Sweets, Desserts, and Other Carbohydrates list with other carbohydrate-containing foods as associated calorie content may be higher.


To prepare for the “Plating a Traditional Meal” activity, the facilitator purchased a pre-made traditional meal at a local Costco Wholesale store prior to session three. The meal consisted of “carne asada” flank steak, rice, beans, salsa, broccoli and water with slices of lemon. The day of session three, the facilitator prepared the pre-made traditional meal at the facilitator’s home kitchen. All foods were prepared or cooked based on
package instructions. Proper safety and sanitation procedures were followed. After the “carne asada” flank steak was baked, it was measured and cut into two-ounce portions. The flank steak was then transferred to a hot plate container. The rice, beans, and broccoli were heated on the stovetop and were also transferred to individual hot plate containers. The hot plates were transferred to the facility and set up in the common communal living kitchen area before the start of session three.

**“CREATE YOUR PLATE”**
~Plating a Traditional Meal~
Fat gram goal = 42 grams per day
Calorie goal = 1500 per day

![Create your plate diagram](image)

*Figure 2. Create your plate.*
Source: Adapted from Rizor et al., 1998.
DPP component. A modified version of “Healthy Eating” was chosen for session three. The session reviewed the importance of regular meal patterns, eating slowly and serving smaller portion sizes (Healthy Eating-Page 1). Like the DPP curriculum, participants were informed about the different food groups, individual portion sizes, and recommended daily serving sizes in each food group. However, it is important to note that the DPP Food Guide Pyramid review and meal planning activities (Healthy Eating-Pages 2-7) were replaced with lesson plans and meal planning activities that used the diabetic exchange list and plate method concept to teach meal planning to participants.

DM component. The food guide pyramid review was replaced with a simplified version of the diabetic exchange list, which emphasized food group categories and portion sizes; however carbohydrate counting was not covered (Daly, 2008). Participants were provided with a “Food Group & Portion Sizes” handout and food models were used to stress the importance of portions sizes in relation to weight loss and blood sugar management. Participants were also taught how to estimate portion sizes using their hands. For example, participants were informed that the size of their palm was equivalent to three ounces of cooked meat (American Diabetes Association, 1991). For the “Create Your Plate” activity, participants were asked to look at their “Create Your Plate” handout and use food models to create a lunch plate. For example, participants with a 42gram fat/1500 calorie goal were allotted six ounces of meat or meat substitutes per day. If a participant chose a three-ounce food model of chicken, they were asked to write down how many more servings they were allotted for the day in that particular food group.

Culturally sensitive component. The “Plating a Traditional Meal” activity was developed by the facilitator to ensure a culturally sensitive intervention and to enforce the
plate method concept. After the completion of the “Create Your Plate” activity, participants were asked to form a line at the kitchen counter with their “Create Your Plate/“Plating a Traditional Meal” handout. Participants who did not want to eat the meal were asked to observe the activity. The facilitator proceeded to ask the participants what the portion sizes were for each food item being served. The facilitator then served each participant 1-2 portions of each food item based on their individual recommended serving sizes. The foods were served with measuring cups that contained scoopers at the ends.

**SCT component.** 1) Goals and Expectancies: A modified version of the DPP, “To Do by Next Week” was developed. The weekly goals and expectations of session three were discussed with participants. Participants were expected to practice the “Create Your Plate” method and measure portion sizes. Participants were also expected to continue “tracking” their fat grams on at least one or more days and continue walking for 30 minutes on at least five days a week. 2) Modeling: At the start of the “Create Your Plate” activity, a participant from the group was asked to demonstrate how to create a lunch plate with the available food models. A participant was also asked to volunteer for the “Plating a Traditional Meal” activity and indicate the portion sizes of each of the food items being served by the facilitator.

**Session 4**

Prior to session four, the facilitator developed a total of four nutrition bingo games. This activity was developed by the facilitator to reinforce lesson plans one through three, and for the purpose of incorporating an activity familiar to the elderly population. A total of four nutrition bingo games were developed. The bingo game topics included the following: Fats, Benefits of Physical Activity, Food Groups, and Portion
Sizes. A total of twenty-five words and phrases pertaining to the game topics were randomly added to a list and numbered one through twenty-five. These words were added to a standardized bingo game format and rotated throughout twenty-five different squares on the bingo game format. The word in the center was removed and considered a free space. This was done a total of eight times creating eight different bingo games for each topic.

**DPP component.** A modified version of “Tip the Calorie Balance” was chosen for session four. The session reviewed the importance of calorie balance in relation to weight loss (Tip the Calorie Balance-Pages 1-3), however specific calorie guidelines and goals were not provided to participants. Instead, participants were encouraged to reduce calories by reaching their fat gram goals, but were not encouraged to focus on calorie intake. The calorie amount that correlated with the fat gram goals were however, factored into the recommended daily serving sizes when designing the “Create Your Plate” and “Plating a Traditional Meal” handout/activity (Session 3). The “Changes you’ve made so far” written activity (Tip the Calorie Balance-Page 4) was not conducted during session four however, the questions in this activity were verbally discussed with each participant during their week-four weight assessments. During the week-four weight measurements, the facilitator compared the weights taken at week four with each of the participants’ baseline weight measurements. Weight measurements were conducted using the methods described in the anthropometric measures section. After weights were recorded by the facilitator in the participants’ tracking packet, participants were informed about whether their weight decreased, increased, or stayed the same. If body weight stayed the same or increased, the facilitator then asked each participant why they thought there was not a
change in weight status. The facilitator then guided each of the participants into
developing a new plan of action to meet the expected weight loss goals. Physical activity
and fat intake goals were reinforced. The participants who lost the expected percentage of
weight loss (2.5%) at this stage were encouraged to continue with their physical activity
and fat gram goals.

**DM component.** A series of four nutrition bingo games replaced the “Changes
you’ve made so far” activity during session four (Tip the Calorie Balance – Page 4).
Participants were asked to partner with one other participant. Packets of bingo game
cards were distributed to each team and the facilitator explained the instructions of the
game to the participants. For each game, the facilitator chose a random number from the
randomized bingo list and proceeded to call out the word/phrase next to the number.
Participants circled their game card if their card contained the word/phrase called out by
the facilitator, and participants were asked quiz like questions about the word/phrase
being discussed. Food models and food items/packages used in session one, were again
used to reinforce portion sizes and fat grams. For example, if the facilitator called out the
word, “olive oil” participants were asked if they remembered the portion size or fat
content in that particular food item. The facilitator reinforced or corrected the answer by
holding up the food model and/or food item for each of the foods items discussed.
Individual prizes were given to each of the team members that won the nutrition bingo
games. Throughout the four bingo games, the facilitator reinforced the importance of
how fat intake, types of foods, portion sizes, and physical activity effect weight and
glycemic control.
Culturally sensitive component. The same traditional food items and packages that were used as examples in session one (Be a Fat Detective) were used as displays in the bingo games. The nutrition facts on each of the food items were printed in both English and Spanish. Examples of food items included the following: packaged pan dulce, packaged chorizo, canned beans (full fat and low fat), milk (whole and 1%), tortillas (corn and flour), butter, and cooking oils (monounsaturated and polyunsaturated).

SCT component. 1) Goals and Expectancies: A modified version of the DPP, “To by Next Week” was developed. The weekly goals and expectations of session four were discussed with participants. Participants were expected to eat fewer calories by eating less fat, focus on their weight loss goals, and continue to track their fat grams and activity. 2) Modeling and Practicing: Throughout the bingo games, volunteers from the group were asked quiz like questions about what they remembered and learned from sessions one through three.

Session 5

Prior to session five, the facilitator reviewed all written informative evaluations questionnaires completed by participants at the end of session four. While the majority of participants did not have any preferences on session topics, one participant asked the question, “Can I still eat deserts and loose weight.” This prompted the facilitator to create a lesson plan focusing on fat and sugar intake. The lesson plan followed the same key principles of the DPP session, “Three Ways to Eat Less Fat” however, included both high-fat and high-sugar foods and dessert items.

A modified diabetic oatmeal cookie was prepared and baked at the facilitator’s home kitchen prior to session five. Proper safety and sanitation procedures were
followed. The diabetic cookie used Splenda® brown sugar as a sugar substitute and replaced ½ the amount of butter with unsweetened applesauce. The recipe was obtained from the Internet at food.com (http://www.food.com/recipe/diabetic-oatmeal-raisin-cookies-144639). In preparation of the nutrition facts labeling reading activity, the facilitator purchased numerous dessert food items at a local Mexican market. These items included the following: packaged pan dulce, tres leche, and arroz con leche.

**DPP component.** A modified version of “Three Ways to Eat Less Fat” was chosen for session five. Due to the written informative evaluation finding and the need to address the role of sugar intake and its effect on weight and glycemic control, the facilitator incorporated a sugar component into the lesson plan. Therefore, DPP title was changed from “Three Ways to Eat Less Fat” to “Three Ways to Eat Less Fat and Sugar.” The three components of eating less fat and sugar included the following: 1. Eat high-fat and high-sugar foods less often, 2. Eat smaller amounts of high-fat and high-sugar foods, 3. Modify dessert recipes. For the ways to eat lower-fat and lower-sugar foods, participants were informed on how to modify recipes to reduce the fat and sugar content of dessert items when baking. The samples of the bite size diabetic oatmeal cookies made with Splenda® were provided to participants at this time. The DPP, menu make-over activity (Three Ways to Eat Less Fat – pages 4-6) was replaced with a nutrition facts label reading activity (Be a Fat Detective – page 7). Participants were taught how to identify the grams of sugar on a nutrition facts label and volunteers were asked to read the sugar and fat content of popular packaged dessert items. The DPP activity, “guess the amount of fat” (Three Ways to Eat Less Fat – Page 1), was replaced with a “guess the amount of sugar,” activity, which followed the same method of the DPP activity.
Participants were shown pictures of a variety of different food items. Participants were asked to write down the food items shown, and then guess the grams of sugar in each of the food items. After each participant was done writing down their answers, the actual grams of sugar in each of the food items were revealed to the participants.

**DM component.** A brief overview of the nutrient content of desserts and the effects of sugar on weight and glycemic control were discussed. Participants were shown a blood glucose and insulin chart indicating normal blood glucose and insulin levels (Funnell, 2009). An explanation of how blood sugar and insulin reacts to excess sugar intake was displayed on the chart. Participants diagnosed with DM were asked about their fasting and postprandial blood glucose target ranges and management/monitoring practices. Participants were also informed about the diagnostic criteria for pre-diabetes (American Diabetes Association, 2011). The health risks associated with high blood sugar in both the diabetic and pre-diabetic ranges were emphasized.

**Culturally sensitive component.** Packaged traditional desserts items were used as examples for reviewing fat and sugar content on food labels. Nutrition facts on each of the food items were printed in both English and Spanish. Examples of food items included the following: packaged pan dulce, ice cream, tres leche, and arroz con leche.

**SCT component.** 1) Goals and Expectancies: A modified version of the DPP, “To Do by Next Week” was developed. The weekly goals and expectations of session five were discussed with participants. Participants were expected to read food labels and write down the total grams of fat and sugar eaten in one or more days. Participants, who were not able to find the fat and/or sugar content of a food item, were encouraged to check out the tracking book in the social service coordinators office and ask the facilitator
to help them at the next meeting. Participants diagnosed with DM were encouraged to monitor their blood sugar on a daily basis. Participants were also expected to continue being active for at least 30 minutes on five days a week.

2) Modeling and Practicing:
During the nutrition facts activity, participants were asked to take a food item from the display and were taught how to read the sugar content on the food label. Volunteers were then asked to share with the group the amount of sugar grams their sample food item contained. During the “guess the amount of sugar” activity, volunteers were also asked to share their “guess” on the amount of sugar the picture food item contained.

Session 6
Prior to session six, the facilitator created a lesson plan focusing on fiber intake. The lesson plan developed by the facilitator was titled, “The Health Benefits of Fiber” and included an activity called, “Guess the Amount of Fiber.” A list of the top fiber-rich foods was used to create the activity (Palmer, 2008). The facilitator selected between three to five high fiber foods from each of the following “The Top Fiber-Rich Foods List” food categories: Fortified foods, beans, berries, whole grains, green vegetables, squash, potatoes, everyday fruits, exotic fruits, and nuts & seeds. The food categories and associated high fiber food items were hand written vertically onto bright colored tag boards. The items were written in Spanish. Each of the food categories and associated high fiber food items were assigned a specific tag board color. Small pieces of excess tag board were cut and labeled with numbers. Pieces of Velcro were attached to the back of the number cards and next to the items listed on the different tag boards. The numbers were placed into a basket. An answer key was developed by the facilitator and was attached to the back of the session handouts. In preparation of providing a visual display
of high fiber foods discussed in the “Guess the Amount of Fiber” activity, the facilitator purchased numerous food items at a local supermarket. These items included the following: beans (black and pinto), rice (brown vs. white), Mexican squash, guava, avocado, jicama, chayote, raspberries, blackberries, broccoli, kale, sweet potato, figs, pinon nuts and almonds. The food items were placed in a display basket and brought to session six. A high fiber quinoa salad was prepared at the facilitator’s home kitchen the day of session six. Proper safety and sanitation procedures were followed. The quinoa salad recipe was obtained from the internet at Karmatarian.org (http://karmatarian.wordpress.com/2010/04/22/black-bean-corn-avocado-salad-over-red-quinoa-with-cilantro-dressing-2). The quinoa salad was placed into a portable ice chest and brought to session six.

**DPP component.** A modified version of “Talk Back to Negative Thoughts” was chosen for session six. A group dialogue on how negative thoughts influence DPP lifestyle goals i.e., weight loss, fat grams goals, and blood sugar management were discussed among participants (Talk Back to Negative Thoughts – pages 1). Positive solutions to negative thoughts were also discussed (Talk Back to Negative Thoughts – page 2). Due to time constraints, the written activity (Talk Back to Negative Thoughts – page 3) was not conducted, however was included in the verbal group dialogue.

**DM component.** The health benefits of fiber in relation to weight, blood sugar, and other health conditions were discussed with participants. Participants were informed about the recommended daily fiber intake (grams) for men and women ages 50 years and older. After the brief discussion on the health benefits of fiber, participants were asked to
pair up in groups of three to participate in the “Guess the Amount of Fiber” activity. The basket of fruits and vegetables and high fiber food items purchased prior to session six were displayed in the middle of a table, and the tag boards were placed on an easel. The facilitator then distributed the colored coded number cards and explained the activity instructions to the teams. Participants were asked to attach the number cards next to the highest fiber food items listed on the tag board. After each game, the facilitator asked the participants to look at their answer key and a brief discussion on the fiber content of each food category and food items were discussed. The food items on display were used as examples to reinforce the importance of fiber intake. The sample of quinoa salad was provided to participants at the end of the activity.

**Culturally sensitive component.** Traditional foods items were selectively chosen from the “Top Fiber-Rich Foods List” (Palmer, 2008) and were included in the, “Guess the Amount of Fiber” activity. These food items were on display during session six and included the following: beans (black and pinto), rice (brown vs. white), Mexican squash, guava, avocado, jicama, chayote, and pinon nuts.

**SCT component.** 1) Goals and Expectancies: A modified version of the DPP, “To Do by Next Week” was developed. The weekly goals and expectations of session six were discussed with participants. Participants were expected to try to reach the recommended daily fiber intake and add up the amount of fiber eaten in one or more days. Participants, who were not able to find the fiber content of a food item, were encouraged to write down the food item anyway and ask the facilitator at the next meeting. Participants were also asked to practice identifying negative thoughts and “stopping” them with positive thoughts. Participants were also expected to continue with
their weight loss and exercise goals. 2) Modeling and Practicing: During the “Talk Back to Negative Thoughts” activity, volunteers were asked to share some of the challenges faced with meeting weight loss and glycemic management goals. During the “guess the amount of fiber” activity, participants were also asked to work as a team and attach their number card next to the food item listed on the tagboards.

Session 7

At end of session six, the facilitator asked participants, which type of traditional meal they would like to have modified. This prompted the facilitator to modify a traditional cheese chili relleno recipe and develop an activity called, “Modifying a Traditional Meal – Guess the Difference.” An internet search for a traditional cheese chili relleno recipe and a low-fat modified version of a chili relleno recipe was conducted. The traditional cheese chili relleno recipe was obtained from the internet at foodnetwork.com ([http://www.foodnetwork.com/recipes/chile-relleno-recipe/index.html](http://www.foodnetwork.com/recipes/chile-relleno-recipe/index.html)), and the low-fat chili relleno casserole was obtained from grouprecipes.com ([http://www.grouprecipes.com/37296/low-fat-chili-relleno-casserole.html](http://www.grouprecipes.com/37296/low-fat-chili-relleno-casserole.html)). The nutrient content of the traditional cheese chili relleno recipe and the modified low-fat chili relleno casserole were both analyzed for total calories, fat, carbohydrates, sugars, fiber, sodium, and protein. The nutrient content of a serving of refried pinto beans, pinto beans prepared without oil, traditional Mexican rice, and Mexican rice prepared without oil, were also analyzed. The nutrition facts were obtained from a nutrition facts label and by using the CalorieKing handbook (Borushek, 2011). The nutrition facts data for a serving of the traditional cheese chili relleno recipe, refried pinto beans, and traditional Mexican rice (traditional Chili Relleno Meal), and the modified low-fat chili relleno casserole, pinto
beans, and Mexican rice (modified low-fat home cooked meal) were calculated and compared. The nutrition facts data (calories, fat, carbohydrate, sugars, fiber, sodium, and protein) for each of the “meals” were handwritten onto the back of neon colored tagboards, and the phrases “Traditional cheese chili relleno meal” or “Low-fat modified home cooked meal” were written on the front of the tag boards that corresponded with the nutrition facts data. Each of the different nutrition facts data (calories, fat, carbohydrate, sugars, fiber, sodium, and protein) was assigned a specific tagboard color. The items were written in Spanish. A game card and an answer key were developed by the facilitator and attached to the session handouts. The low-fat chili relleno casserole was prepared at the facilitator’s home kitchen the day of session seven. Proper safety and sanitation procedures were followed. The low-fat chili relleno casserole was placed in a heat resistant container and brought to session seven.

**DPP component.** A modified version of “Four Keys to Healthy Eating Out” was chosen for session seven. The session reviewed the “Four Keys to Healthy Eating Out, “How to ask for what you want,” and “What’s on the menu?” (Four Keys to Healthy Eating Out – Pages 1 - 4). The section, “Fast foods can be lower in fat” (Four Keys to Healthy Eating Out – Pages 5-6) was not reviewed. Instead, an open discussion focusing on foods items at restaurants in the surrounding area, and restaurants often frequented by some participants in the group, e.g., King Taco and Home Town Buffet, were discussed.

**DM component.** The difficulties of managing blood sugar and weight due to hidden sugars and fats in many restaurant meals/recipes were discussed. The benefits of good blood sugar control in both the diabetic and pre-diabetic ranges were emphasized.
Culturally sensitive component. To maintain a culturally sensitive intervention, the activity, “Modifying a Traditional Meal – Guess the Difference” was developed by the facilitator. Participants were asked to look at their “Modifying a Traditional Meal – Guess the difference” game card handout and write down (guess) the amount of calories, fat, carbohydrates, sugars, fiber, sodium, and protein for each of the “meals.” The facilitator then held up the neon color tagboards for each of the “meals” and corresponding nutrition facts, and asked volunteers from the group to share their nutrition facts answers. After the participants were done sharing their answers, the facilitator then turned the tagboards over and revealed the nutrition facts information to the group. At the end of the activity participants were invited to try the low-fat chili relleno casserole recipe. Participants were informed on how traditional recipes can be modified to reduce fat and calories. A handout providing a list of how to substitute high-fat foods for low-fat foods in recipes was provided to participants.

SCT components. 1) Goals and Expectancies: A modified version of the DPP, “To Do By Next Week” was developed. The weekly goals and expectations of session seven were discussed with participants. Participants were expected to choose/try a low fat menu item at their next restaurant visit and apply the principles of the “Four Keys to Eating Out.” Participants were asked to write down the restaurant menu item chosen, the challenges they faced and how they were resolved. Participants were encouraged to modify a recipe using low-fat food substitutions, and were again encouraged to continue with their weight loss and exercise goals. 2) Modeling and Practicing: During the “Modifying a Traditional Meal – Guess the Difference” activity volunteers were asked to share their nutrition facts answers for each of the meals nutrition facts.
Session 8

Prior to session eight, the facilitator reviewed all written informative evaluations questionnaires completed by participants at the end of session seven. While the majority of participants did not have any preferences on session topics, two participants wanted to learn more about lean cuts of meats and preparation methods. This prompted the facilitator to develop an activity called, “Cooking Low-Fat Traditional Meals.” An Internet search for traditional low-fat recipes was conducted and based off of participants food preferences. The aim of the search was to find traditional low-fat recipes that included a source of lean protein, a carbohydrate/starch, a fruit, a vegetable, and a healthy fat. For the lean protein and fruit source, the facilitator chose a “Grilled Mahi Mahi with Tomatillo and Mango Salsa” recipe, which was obtained from the FoodNetwork.com (http://www.foodnetwork.com/recipes/aaron-sanchez/grilled-mahi-mahi-with-tomatillo-and-mango-salsa-recipe/index.html). For the carbohydrate/starch source, the facilitator chose both a “Spiced Pinto Bean” recipe and a “Mexican brown rice” recipe. The “Spiced Pinto Bean” recipe was obtained from EatingWell.com (http://www.eatingwell.com/recipes/spiced_pinto_beans.html), and the “Mexican brown rice” recipe was obtained from www.cookusinterruptus.com (http://www.cookusinterruptus.com/index.php?video_id=88). For the vegetable and healthy fat source, a “Mexican Spinach Salad” recipe was chosen and was obtained from Food.com (http://mexican.food.com/recipe/mexican-shrimp-spinach-salad-19972).

After all recipes were chosen, the facilitator purchased the ingredients needed for each recipe at different local markets, and all items were stored at the facilitator’s home kitchen. The facilitator reviewed each recipe to determine which items could be prepared
prior to session eight. Proper safety and sanitation procedures were followed. The following recipe food items were prepared the day before or the day of session eight:

- **Grilled Mahi Mahi with Tomatillo and Mango Salsa**
  - 12 ounces of frozen mahi mahi was defrosted overnight in the refrigerator. The defrosted mahi mahi was placed into a plastic Ziploc freezer bag and marinated for four hours in the refrigerator. The mahi mahi was placed in a portable ice chest labeled seafood products.

- **The Tomatillo Mango Salsa (see recipe)** was prepared at the facilitator’s home kitchen the day of session eight, transferred to a sealed tight container and placed into a portable ice chest labeled fresh fruits and vegetables.

- **Mexican Spinach Salad**
  - All ingredients required for the salad (see recipe) were washed and prepared according to recipe instructions the day of session eight. All fruits and vegetables were then transferred to separate sealed tight containers and placed into a portable ice chest labeled fresh fruits and vegetables.
  - All ingredients required for the salad dressing (see recipe) were prepared according to recipe instructions the day of session eight. All fresh ingredients were then transferred to a sealed tight container and placed into a portable ice chest labeled fresh fruits and vegetables. All dry ingredients, oil, and mixing devices (blender and whisk) were packed into a shopping bag.

- **Spiced pinto beans recipe**
The Spiced Pinto bean recipe (see recipe) was prepared according to recipe instructions the day of session eight. The beans were then transferred to a hotplate.

Mexican brown rice recipe

The Mexican brown rice recipe (see recipe) was prepared according to recipe instructions the day of session eight. The rice was then transferred to a hotplate.

To enforce the cooking demonstration activity, the facilitator developed a handout titled “Cooking Low-fat Traditional Meals,” and included the following five key learning components: 1. Choose a Recipe 2. Use your Plate to Plan your Meal 3. Choose lean meats or meat substitutes instead of high fat meats 4. Practice low-fat cooking methods 5. Keep your blood sugar in control. To prepare for the study commencement, award certificates folders were prepared for each participant.

**DPP component.** A modified version of “Ways to Stay Motivated” was chosen for session eight. Prior to the cooking demonstration, the facilitator initiated a brief group dialogue on the importance of staying motivated. The eight ways to stay motivated were incorporated into the group discussion (Ways to Stay Motivated – pages 1-4). The “Progress Review” (Ways to Stay Motivated – Page 1) was verbally discussed with participants during their week-eight weight assessments. During the week-eight weight measurements, the facilitator compared the weights taken at week-four with each of the participants’ week-eight weight measurements. Weight measurements were conducted using the methods described in the anthropometric section. After weights were recorded by the facilitator in each of the participants’ individual tracking packets, participants were
informed about whether their weight decreased, increased, or stayed the same. If body weight stayed the same or increased, the facilitator then asked each participant why they thought there was not a change in weight status. The facilitator then guided each of the participants into developing a new plan of action to meet their expected weight loss goals. Physical activity and fat intake goals were reinforced. The participants’ who lost the expected percentage of weight loss (5.0%) were encouraged to continue with their physical activity and fat gram goals.

**DM component.** The importance of meal planning and meal timing was discussed with participants. Participants were encouraged to modify recipes and use the plate method when planning and serving meals. A discussion about consistent carbohydrate intake in relation to blood glucose stabilization was also emphasized.

**Culturally sensitive component.** To ensure a culturally sensitive intervention, the facilitator developed the activity, “Cooking Low-Fat Traditional Meals.” During the cooking demonstration, all prepared food and ingredients were removed from their designated ice chests and set up in the kitchen area of the communal living room. Cooking demonstrations for each of the low-fat traditional recipes was conducted. Participants were invited to sample the food items after the entire cooking demonstration was completed. At the end of session eight, the facilitator conducted a commencement ceremony. The facilitator called each of the participants’ names, congratulated them for attending the lifestyle intervention, and handed them their commencement packet.

**SCT component.** 1) Goals and Expectancies: A modified version of the DPP, “To Do By Next Week” was developed. The weekly goals and expectations of session eight were discussed with participants. Participants were encouraged to practice the eight
motivational techniques described in the DPP group discussion. Participants were also encouraged to practice modifying low-fat traditional meals utilizing the five key components to “Cooking Low-Fat Traditional Meals.” Participants were again encouraged to continue with their weight loss and exercise goals. 2) Modeling and Practicing: During the “Cooking Low-Fat Traditional Meals” activity, volunteers were asked to assist the facilitator in cooking and assembling the recipes. Other volunteers from the group were asked to serve sample food items to each of the participants using the plate method concept.

Qualitative Assessment

Purpose

A focus group methodology was used to collect qualitative data from subjects who participated in the diabetes prevention and management lifestyle intervention. The purpose of the focus group was to gain an understanding of participant opinions regarding the study curriculum (modified DPP and additional developed curriculum), and evaluate the effectiveness of the overall intervention. To assess the study curriculum, subjects were asked questions about what they liked and disliked about the classes as well as what they learned and how the intervention could be improved.

Participant Recruitment

All study participants who attended the diabetes prevention and management lifestyle intervention were eligible to participate in the focus group study. Focus group invitations and consent forms were delivered to each of the study participants at both TELACU assisted living facilities (Manor and CASA) one week prior to the scheduled focus group meetings. Participants interested in joining the study were asked to turn in
their consent forms to their Social Service Coordinator prior to their scheduled focus group meeting. A total of 27 participants (Manor n=6; CASA n=21) were invited to attend. Due to the large participant group at CASA, consistent attenders (n=15) and non-consistent attenders (n=12) were separated and invited to different focus group meetings. Of the six participants invited to the Manor focus group, two were non-consistent attenders. These two non-consistent attenders however, did not attend the focus group interview. Consistent attenders were those participants who attended at least five of the eight sessions offered.

**Focus Group Study Design**

The principal investigator (DrPH, MPH, RD), who had extensive training in developing, conducting, and analyzing qualitative assessments, designed a series of basic focus group interviewing questions. Focus group questions are presented in Table 9. These questions followed Krueger’s guidelines (Krueger, 1994), and also met the recommended guidelines for designing focus group questions for an older population (Langford & McDonagh, 2003).

The Social Service Coordinator (SSC), who assisted the study facilitator in Spanish translation throughout the entire intervention (Manor facility), was trained to moderate and conduct the focus group interviews. The SSC, who holds a master’s degree in education, was chosen to conduct the focus group interviews due to having experience in serving and educating the elderly Hispanic population on numerous social and health related issues. One week prior to the intervention, the study facilitator reviewed the focus group procedures with the SSC and a one-on-one mock focus group was conducted.
The SSC was also trained on how to properly use the Olympus DS-30 digital voice recorder (Olympus Imaging America Inc, Center Valley, PA, 2005-2008).

Three focus groups were held during the last week of June 2011 each with 3-8 participants. One focus group was held at the TELACU Manor living facility (consistent attenders; n=3) and two focus groups (consistent attenders; n=8 and non-consistent attenders; n=4) were held at the TELACU CASA living facility. The Social Service Coordinator managing the TELACU Manor living facility conducted all three focus groups based on standardized methods developed by Krueger and Creswell (Krueger, 1994; Creswell, 1998). Additional methods were utilized to ensure the focus group was conducted in a manner necessary to meet the needs of older participants (Langford & McDonagh, 2003). The SSC audiotaped the entire focus group interviews and study participants were asked a series of five questions (Table 9) regarding the diabetes study curriculum and intervention. The focus group process lasted between 45-60 minutes.

Table 9

<table>
<thead>
<tr>
<th>Question 1.</th>
<th>What did you think of the class?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 2.</td>
<td>What did you learn from the class?</td>
</tr>
<tr>
<td>Question 3.</td>
<td>What did you like most about the class?</td>
</tr>
<tr>
<td>Question 4.</td>
<td>What did you like least about the class?</td>
</tr>
<tr>
<td>Question 5.</td>
<td>How could the class be improved?</td>
</tr>
</tbody>
</table>

Data Analysis

A paid nutritionist fluent in both English and Spanish transcribed the digital recordings verbatim. The principle investigator and the diabetes study facilitator
reviewed the transcribed data and identified themes using the constant comparative method, an analytic technique first described by Glaser and Strauss (Glaser & Strauss, 1967) and later expanded on by Neuendorf (Neuendorf, 2002).
CHAPTER IV
RESEARCH FINDINGS

Participants

A total of 32 eligible TELACU residents (Manor and CASA) enrolled in the study. There were eight initial enrollments at the Manor facility and 24 enrollments at the CASA facility. Participants who attended only two class sessions were considered dropouts. There were a total of five dropouts; two from the Manor group and three from the CASA group. Participants reported dropping out of the study for the following reasons: 1. family problems (n=1), medical issues (n=2), program difficulty (n=1), and scheduling conflicts (n=1). After accounting for attendance rates, a total of 12 participants (non-consistent attenders) did not meet the attendance eligibility criteria of attending at least 5 of the eight sessions offered, with the majority of non-consistent attenders belonging to the CASA group (n=10).

A total of 15 participants (consistent-attendees) completed the study (Manor n=5; CASA n=10). The descriptive characteristics of the final participants from both facilities combined are summarized in Table 10. The participants were 15 Hispanic men (n=3) and women (n=12) aged 61-84 years. The mean age of the study subjects was 72 years (mean = 72.1). There were a higher percentage of type 2 diabetic participants (n=7) compared to those with prediabetes (n=4). Four participants were overweight and did not exhibit signs of elevated fasting capillary blood glucose throughout the entire study (n=4). All participants had a BMI greater than 24 kg/m² with the highest percentage of participants in the obese category. Twelve of the 15 subjects’ primary language was Spanish.
Table 10

*Baseline Participant Characteristics*

<table>
<thead>
<tr>
<th>Variables</th>
<th>N=15</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60-69</td>
<td>6</td>
<td>40%</td>
</tr>
<tr>
<td>70-79</td>
<td>6</td>
<td>20%</td>
</tr>
<tr>
<td>80-89</td>
<td>3</td>
<td>20%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>80%</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>20%</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>7</td>
<td>47%</td>
</tr>
<tr>
<td>Prediabetes</td>
<td>4</td>
<td>27%</td>
</tr>
<tr>
<td>Overweight only</td>
<td>4</td>
<td>27%</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-29 (overweight)</td>
<td>5</td>
<td>33%</td>
</tr>
<tr>
<td>30-39 (obese)</td>
<td>6</td>
<td>40%</td>
</tr>
<tr>
<td>40-46 (extremely obese)</td>
<td>4</td>
<td>27%</td>
</tr>
<tr>
<td>Language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spanish speaking</td>
<td>12</td>
<td>80%</td>
</tr>
<tr>
<td>English speaking</td>
<td>3</td>
<td>20%</td>
</tr>
</tbody>
</table>

Overall, attendance rates were fairly good, ranging from 11 to 14 participants at each of the eight sessions offered. Attendance rates for all of the eight sessions offered ranged from 73-93% throughout the entire intervention with an average attendance rate of 80%. The total number of participants that attended each session are displayed in Table 11 and further categorized by facilities.
Table 11

*Modified DPP Sessions and Attendance Rates for TELACU Manor & Casa Participants*

<table>
<thead>
<tr>
<th>Session</th>
<th>MANOR n=5</th>
<th>CASA n=10</th>
<th>Total n=15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1: Welcome to the Lifestyle Balance Program &amp; Be a Fat Detective</td>
<td>n=5</td>
<td>n=10</td>
<td>n=15</td>
</tr>
<tr>
<td>Session 2: Being Active: A Way of Life</td>
<td>n=5</td>
<td>n=8</td>
<td>n=13</td>
</tr>
<tr>
<td>Session 3: Healthy Eating</td>
<td>n=3</td>
<td>n=9</td>
<td>n=12</td>
</tr>
<tr>
<td>Session 4: Tip the Calorie Balance</td>
<td>n=4</td>
<td>n=9</td>
<td>n=13</td>
</tr>
<tr>
<td>Session 5: Three Ways to Eat Less Fat</td>
<td>n=5</td>
<td>n=9</td>
<td>n=14</td>
</tr>
<tr>
<td>Session 6: Talk Back to Negative</td>
<td>n=4</td>
<td>n=7</td>
<td>n=11</td>
</tr>
<tr>
<td>Session 7: Four Keys to Healthy Out</td>
<td>n=3</td>
<td>n=9</td>
<td>n=12</td>
</tr>
<tr>
<td>Session 8: Ways to Stay Motivated</td>
<td>n=4</td>
<td>n=8</td>
<td>n=12</td>
</tr>
</tbody>
</table>

Descriptive results for baseline measures are summarized in Table 12. Data are presented descriptively as mean ± SD for week 0 (baseline). Data for anthropometric measures at baseline was available for 14 of the 15 participants. One participant (consistent-attender) joined the study on the day of session one, and therefore baseline measures were not available for this participant. Study subjects mean weight ranged from 130.0 – 311.5 lbs (mean = 181.50, SD = 45.527), and BMI ranged from 25-46 kg/m² at baseline (mean = 33.13, SD = 6.789). The mean percent body fat ranged from 29.9-53.4 % (mean= 42.20, SD =7.080). Data for fasting capillary blood glucose (mg/dL) was available for only five participants. This was due to some participants having eaten prior to testing and the lack of an available registered nurse on re-scheduled assessment days. Fasting blood glucose levels for the five participants ranged from 94 -118 mg/dL (Mean = 105.60, SD = 11.327).

Table 13 summarizes the changes in body weight (lb.), BMI kg/m², percent body fat and capillary fasting blood glucose from baseline to 12-weeks. Data was available for 12 of 15 participants. One participant was not available for baseline measures and two were not available for final measures. At week 12, there were significant reductions in
mean weigh (2.63 lbs., p<.002) compared with baseline, and this was associated with a
decrease in BMI (0.51kg/m kg/m² p<.001). Percent body fat did not decrease
significantly. Capillary fasting blood glucose levels were not assessed due to lack of data.

Over the course of the study, none of the participants reached the 5% weight loss
goal at 12-weeks. Table 14 displays the total percent of weight lost or gained for each
participant from baseline to 12-weeks. Data is presented for 12 of the 15 participants.
Total weight loss ranged from 2lbs. to 5.5lbs., with three participants achieving a weight
loss of ≥5lbs. Two participants weight slightly increased over the course of the
intervention ranging 0.5 – 1.0lbs. The majority of participants (67%) lost between
1 – 2.7% of their baseline body weight at the end of the intervention. The participant with
the highest percent weight change reached a 3.38% loss, which was 2.63lbs below a 5%
weight loss.

Table 14

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, lb</td>
<td>14</td>
<td>130.0</td>
<td>311.5</td>
<td>181.50</td>
<td>45.527</td>
</tr>
<tr>
<td>BMI, kg/m</td>
<td>14</td>
<td>25</td>
<td>46.0</td>
<td>33.13</td>
<td>6.789</td>
</tr>
<tr>
<td>Percent body fat,%</td>
<td>14</td>
<td>29.9</td>
<td>53.4</td>
<td>42.20</td>
<td>7.080</td>
</tr>
<tr>
<td>Fasting blood glucose, mg/dl</td>
<td>5</td>
<td>94</td>
<td>118</td>
<td>105.60</td>
<td>11.327</td>
</tr>
</tbody>
</table>

Mean (SD) Baseline Descriptive Statistics for Anthropometric Study Measures
Table 13

Changes in Body Weight, Body Mass Index, Percent Body Fat and Fasting Glucose from Baseline to 12-weeks (n=12)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline, Mean ± SD</th>
<th>12Weeks, Mean ± SD</th>
<th>Mean Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body weight</td>
<td>181.50 ± 47.04</td>
<td>181.86 ± 45.49</td>
<td>-0.36</td>
<td>.002***</td>
</tr>
<tr>
<td>Body mass index</td>
<td>33.31± 7.02</td>
<td>33.92± 6.63</td>
<td>-0.61</td>
<td>.001***</td>
</tr>
<tr>
<td>Total fat, %</td>
<td>42.20 ± 7.36</td>
<td>42.39± 7.84</td>
<td>-0.19</td>
<td>.806</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>105.60 ±11.33</td>
<td>118.67 ± 33.30</td>
<td>-13.07</td>
<td>----</td>
</tr>
</tbody>
</table>

Week 12 data not available for 3 subjects (N=12).

***P<0.05

Table 14

Total Percent Weight Loss or Gain for Each Participant at 12 weeks.

<table>
<thead>
<tr>
<th>Participants N=15</th>
<th>Weight Baseline</th>
<th>Weight Week12</th>
<th>Wt. loss goal of 5%</th>
<th>Weight lost or gained</th>
<th>Percent Wt. loss or gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>311.5</td>
<td>307.5</td>
<td>15.58lbs</td>
<td>↓ 4 lbs</td>
<td>1.28%</td>
</tr>
<tr>
<td>2</td>
<td>159.5</td>
<td>160.5</td>
<td>7.98lbs</td>
<td>↑ 1 lbs</td>
<td>0.63%</td>
</tr>
<tr>
<td>3</td>
<td>184.5</td>
<td>185</td>
<td>9.22lbs</td>
<td>↑ 0.5 lbs</td>
<td>0.27%</td>
</tr>
<tr>
<td>4</td>
<td>187</td>
<td>182</td>
<td>9.35lbs</td>
<td>↓ 5 lbs</td>
<td>2.67%</td>
</tr>
<tr>
<td>5</td>
<td>161.5</td>
<td>ND</td>
<td>8.08lbs</td>
<td>ND</td>
<td>----</td>
</tr>
<tr>
<td>6</td>
<td>130</td>
<td>128</td>
<td>6.50lbs</td>
<td>↓ 2 lbs</td>
<td>1.54%</td>
</tr>
<tr>
<td>7</td>
<td>197.5</td>
<td>195.5</td>
<td>9.88lbs</td>
<td>↓ 2 lbs</td>
<td>1.01%</td>
</tr>
<tr>
<td>8</td>
<td>223.5</td>
<td>218</td>
<td>11.18lbs</td>
<td>↓ 5.5 lbs</td>
<td>2.47%</td>
</tr>
<tr>
<td>9</td>
<td>173.5</td>
<td>173</td>
<td>8.68lbs</td>
<td>↓ 0.5 lbs</td>
<td>0.29%</td>
</tr>
<tr>
<td>10</td>
<td>185</td>
<td>182.5</td>
<td>9.25lbs</td>
<td>↓ 2.5 lbs</td>
<td>1.35%</td>
</tr>
<tr>
<td>11</td>
<td>189.5</td>
<td>187</td>
<td>9.48lbs</td>
<td>↓ 2.5 lbs</td>
<td>1.32%</td>
</tr>
<tr>
<td>12</td>
<td>ND</td>
<td>162</td>
<td>ND</td>
<td>ND</td>
<td>----</td>
</tr>
<tr>
<td>13</td>
<td>130</td>
<td>126.5</td>
<td>6.50lbs</td>
<td>↓ 3.5 lbs</td>
<td>2.70%</td>
</tr>
<tr>
<td>14</td>
<td>145.5</td>
<td>ND</td>
<td>7.26lbs</td>
<td>ND</td>
<td>----</td>
</tr>
<tr>
<td>15</td>
<td>162.5</td>
<td>157</td>
<td>8.13lbs</td>
<td>↓ 5.5 lbs</td>
<td>3.38%</td>
</tr>
</tbody>
</table>

ND, No data available; n=12.

Qualitative questionnaire responses gathered at the end of each session were generally positive and with limited requests for new or additional class topics. In general, participants were interested in leaning more about how to prevent diabetes through
weight loss and/or how to manage blood sugar to prevent diabetes related complications such as kidney disease. Some participants indicated they wanted to learn more about fiber, sugar intake, and lean protein such as seafood. One DPP class topic was modified to meet the request of a participant who asked the question, “Can I still eat desserts and lose weight.” This question, combined with an overall general interest in diabetes prevention and management, prompted the facilitator to develop a class topic focusing on the combination of sugar and fat intake in relation to weight and blood sugar control.

The DPP session, “Three Ways to Eat Less Fat,” was modified to include nutritional information about sugar intake, and was re-titled “Three Ways to Eat Less Fat and Sugar.” This class topic followed the same format and guidelines as the DPP session, while emphasizing how to incorporate traditional dessert items into a healthy diet. The request for information on fiber intake also prompted the facilitator to include a brief lesson and activity on the importance fiber, which was combined with the DPP session, “Talk Back To Negative Thoughts.” Three participants indicated they wanted to learn more about lean cuts of meats such as seafood and therefore, this information was used to choose the recipes prepared during the session eight activity, “Cooking Low-Fat Traditional Meals.”

**Informal Cost Evaluation**

The cost of the 12-week program including eight sessions totaled $1,100.00. The cost per each participant was calculated at approximately $70.00 per participant (n=15). The majority of costs were related to purchasing food items, which were used for taste testing, modeling activities, and cooking demonstrations.
Qualitative Assessment Results

A total of 13 women and two men participated in the focus group study. Of the 15 participants who attended the three focus groups, a total of 11 consistent attenders (Manor n=3; CASA n=8) and four non-consistent attenders (CASA only n=4) participated in the focus group interviews. Eleven of the original 15 subjects who completed the entire diabetes intervention (consistent attenders) participated in the focus group study. The mean age of participants was 74 years ± 12 years. To identify themes, consistent-attenders and non-consistent attenders were analyzed together and separately. When both groups were analyzed together, only one common theme was identified between the two groups. When groups were analyzed separately, a total of five main themes were identified for consistent attenders. A total of two themes were identified for non-consistent attenders.

Consistent Attenders & Non-Consistent Attenders

Themes identified for effective class topics within the curriculum. To ascertain which class topics were most effective, participants were asked to share what they liked and learned most about the intervention. In all three focus group interviews the topic of, portion size was most frequently mentioned among all participants’ (consistent and non-consistent attenders). Participants also described how they liked learning about portions sizes in conjunction with other class topics such as food labels, food preparation (cooking), types of oils, carbohydrates/sweets and exercise as formative topics as well.

Portion Size was identified as the most effective learning topic offered within the curriculum. Participants discussed how learning about portions sizes was helpful in
reducing overeating and improving dietary habits. One participant who shared how she learned that the “quantity” of food was important despite eating organic foods stated:

*I liked that they told us and taught us about the portions we should eat because a lot of times you think that because you are eating organic food it doesn’t matter how much you eat. But the quantity does matter, so I taught myself how to eat better portions. I even bought measuring cups to serve myself. I eat with just my fork and tostada. The portions is what I liked most because I use to eat too much. At night I don’t eat anything...maybe cereal with low fat milk or a banana or a piece of fruit at night nothing else.*

Another participant who shared that her dietary habits “improved” by learning about portion sizes stated:

*For me it was very helpful to learn to eat smaller portions and not to eat sweets, bread, soda, and all of that I have eliminated. I don’t drink soda or eat sweet things...only once in awhile, not how I use to eat. I have improved a lot.*

A participant who mentioned she liked learning about portions in combination with other class topics and stated:

*I also like the classes that were taught here and the way everything was facilitated to teach us about portions and how to combine them, what things to combine with which foods, what to drink as well, what beverages to drink so that they don’t cause us harm. Also how to cook, the manner in which to vary the food preparation for the way we use to prepare it, how to prepare it differently...without fat and without pasta and flour and all the stuff that causes us harm.*

When asked what was learned most from the class (entire intervention) one participant specifically indicated two class topics when she stated:

*The food labels and portion sizes above all.*

**Consistent Attenders**

**Themes Identified for Quality of the Intervention.** To gain a general understanding of participants’ opinions regarding the diabetes prevention and management study, participants were asked to share their thoughts about the intervention.
Two themes were identified regarding the quality of the intervention, and the manner in which the curriculum was facilitated. Participants’ opinions suggested that the intervention was of very high quality and that the curriculum was explained well.

Participants in the consistent-attender group (n=11) all deemed the intervention as being of very high quality. Some participants described the intervention as “excellent” whereas others described the classes as “very informative,” “perfect,” or “helpful.” Other participants’ expressed their gratitude and were thankful for the intervention. The opening question during the interviews (question 1) prompted a series of concise statements. One participant that was eager to speak about the classes stated:

*Can I speak? They were excellent. They were excellent.*

A total of five participants’ responded consecutively to the opening question (question 1.) with the following statements:

- **Statement 1:** Very informative
- **Statement 2:** Excellent
- **Statement 3:** Very good classes that they gave about diabetes.
- **Statement 4:** Very informative
- **Statement 5:** I am very surprised because the classes about the food have been very helpful to me.

When asked to please expand on why the classes were “excellent,” one participant stated:

*I had never heard any of this stuff. I was eating junk food and all of that and so with her I began to pay attention to what I was eating, looking at the food labels and I try not to eat a lot of dessert or things of that nature.*
Another participant stated:

*For me, it was perfect because we received different modes of learning that we could understand perfectly.*

Some participants expressed their gratitude about receiving the intervention. A participant who resided in the facility for over 10 years expressed her gratitude when she shared:

*I am very happy because in all of the years that I’ve lived here, when they opened this place in 1992 no one had come to give us this class. This was the first time that someone was interested in helping us and I am very thankful.*

Another participant shared:

*For me the classes were very interesting and they have helped me a lot. Thank you.*

Participants also indicated that the classes were *explained well*. Participants described how detailed class explanations provided knowledge about diabetes, clarified why specific food products are recommended for diabetes, and explanations provided a means for understanding the curriculum. One participant who did not have prior knowledge about diabetes stated:

*She explained absolutely everything. I didn’t know anything about diabetes and she had the patience and calm and knew how to speak and explain everything. What to eat and how to act.*

Another participant who found the explanations about the nutrient content of different food products helpful stated:

*She explained the content of the products because sometimes we are confused about why a product that we buy in the store is better and she explained to us very well the products that are necessary for our health.*
Another participant who mentioned the classes were explained well stated:

*That she focused a lot on explaining everything and we could understand her. She explained everything well, through speaking and by demonstrating the things she had brought.*

**Themes identified for preventing & managing diabetes.** Two themes were identified for diabetes prevention and management. Participants most commonly discussed the relationship between *better food and health* in terms of disease prevention, improved food choices, and blood sugar management. Participants also discussed the relationship between *exercise and health.*

The relationship between *better food and health* was identified as an important factor necessary for diabetes prevention and management. One participant stated, “I have learned a lot about how to eat overall. That we have respect for ourselves so we can get better.” Participants who utilized the educational tools taught in the curriculum were able to make self-informed decisions about food and health. This was expressed best by one participant who stated:

*Also, another important thing that I liked was that it was a very educational program for us who ignore a lot of things about health. One of the details that I liked very much was that they emphasized that when we go grocery shopping to read the food labels for the amounts of sodium, how many calories it contains, the sugar. In that way you go about informing yourself about health and what you should be eating.*

Participants with diabetes also realized the importance of managing blood sugar. Participants who were struggling with blood sugar issues seemed to grasp an understanding of how better food relates to the prevention of diabetic related diseases. One participant who was struggling with blood sugar issues stated, “I learned quite a bit. I changed the fact that I eat a lot of red meat because it is bad for your diabetes. It has
helped me a lot because my sugar levels have gone down a lot.” Another participant who reflected on her past issues with blood sugar management expressed:

If I had spoken with someone 10 years ago I would have prevented neuropathy, because my sugar fluctuated up and down and I didn’t know things like that. The relationship between exercise and health was also identified as an important factor necessary for diabetes prevention and management. Participants described the relationship between exercise and health as a way to, “battle against disease,” and “control diabetes.” Exercise was also discussed in terms of improving well-being. One participant who shared that the exercise she learned in the intervention significantly helped her stated, “overall she has helped me in the way I eat, also the exercise that she gave us has helped me a lot, it has been perfect, I have felt a lot better.” Participants with diabetes seemed to gain an understanding about the importance of exercise and disease prevention, as shared by one participant who stated:

She also emphasized that apart from the diet, exercise is very important. So to walk at least 30 minutes everyday because in that way we can battle against disease.

Another participant learned:

How to control diabetes by walking, eating small portions, no fat, and to be very cautious with sweets.

Themes identified for curriculum improvement. To determine the changes needed to further develop the curriculum, participants were asked how the classes could be improved. Participants in the consistent-attender group all conveyed the need for a longer amount of sessions. Some participants mentioned that more participation (more residents joining the study) would have improved the sense of community gained through the study and benefited more residents health wise.
The inclusion of a longer amount of sessions was identified as necessary for future interventions in terms of accomplishing goals and achieving long-term success. Participants expressed the need for more classes for the purpose of ensuring accountability and maintaining motivation. The need for more classes to help support the changes of old lifestyle habits was also important, as expressed by one participant who shared, “Yes, I feel the same. I agree with everything. I would like it if the teaching was more constant so that it helps us more. Sometimes we have habits that we’ve had all of our lives, so someone that could remind us about what we are supposed to be doing so that in time we can change out habits and for new ones and change our lifestyle and start anew.” Being accountable for changes in weight status was also viewed as a motivator to achieve weight loss goals, as expressed by another participant who stated:

To continue to ask about how we are doing, if we are losing weight...
I also agree with offering more classes about diabetes. That way we gain more enthusiasm because there would be accountability and she would weigh us and we would be worried about weight more and that way we are more motivated.

Participants also discussed how the continuation of class sessions would provide the motivation needed to prevent failure and allow for continued success. A concern about possible failure was conveyed by one participant who stated:

“For me as well, it would be very good if you continued to give classes about this topic because its motivation for us so that we don’t fail, it helps us stay on track and continue on with the program.”

Another participant who conveyed the need for more classes so she could continue to “move forward” stated:

“I feel good, I continue to go ahead with the food portions and the manner in which she taught us about health. That is why I would like someone to continue to motivate us so we can continue to move forward because there are times when you feel like not coming but we do have to and if there is someone here for us we
will say, no, we have to move forward because if not we might not be able to do it anymore.” But if someone pushes us and motivates us we can move forward.”

Non-Consistent Attenders

Themes identified for low attrition rates. A scheduling conflict was identified as the reason for low attrition rates. Participants indicated that class sessions typically conflicted with scheduled doctors or pharmacy appointments. Participants also felt that if classes were held in the “afternoon” they were more likely to attend class sessions as expressed by one participant who stated, “I think that in the mornings we are all busy, we all go to the doctor. After 2 we are home so we can attend the classes. At 10 or 11 we are not available and when we are not available we miss the classes, but when we are available we come. So after 2 we can be sure to make it to the classes.” Another participant agreed when she stated:

Me too, the schedule. In the morning we go to the doctor or have other appointments. In the afternoon we don’t have appointments.

While participants did not discuss why they prioritized doctors visits over class sessions, one participant who shared that having to re-schedule a doctors visit would be problematic due to appointment availability stated:

Sometimes we couldn’t make it to all the classes because we had other compromises with the doctors in the morning. Sometimes mornings are a bad time to have an appointment here because we all have to go to the doctor’s or the pharmacy. The majority of us are busy in the morning. At 1 or 2 is when we have more time. Sometimes there was a meeting but I had to go see my doctor because if I didn’t see him that day they would give me an appointment in 2 months.

Themes identified as barriers to follow dietary recommendations. Financial issues emerged as the primary barrier to adapting the interventions dietary recommendations. All non-consistent participants indicated that following a specific diet in many ways was too costly.
Participants also mentioned the cost of possible food waste and cost of ingredients for cooking new recipes. One participant stated:

*It was very good, the difference is that sometime you can’t follow a diet exactly how it is because you don’t have the right food or the money to buy the right food.*

Another participant who was concerned about the cost of wasting food such as fruits and vegetables stated:

*It’s hard to follow the diet for many reasons. You have to buy a lot and sometimes you might waste the food you would like to order food that you want to eat so as not to waste food. Like when you buy a lot of vegetables it goes to waste because you don’t eat it all. I buy fruits and vegetables and they go to waste. I can’t eat the same thing every day. I eat a lot of cactus in shakes and in salad. Cactus is my staple food, chicken is also a staple and beans too. Everything else every so often. Sometimes I don’t follow the diet but I try. I do some exercise, I don’t smoke or drink. I have a somewhat healthy lifestyle I think. Sometimes I eat a little more because of a party or for Father’s Day we went out to eat ribs. Sometimes you feel guilty. My sugar is not exactly where it should be but it is okay. It went up to 500. I am not sure why, but I have modified what I have been eating since then.*

Although, the cooking demonstration and food tasting portion of the curriculum was well received by non-consistent attenders, some of these participants felt the cost of ingredients to cook more complicated food recipes was too expensive. One participant who described the food as “delicious,” resorted back to basic and familiar cooking methods due to the cost of ingredients stated:

*She cooked food and it was very delicious. To cook you have to buy a lot of things. Yes, but I see on T.V. that you have to have a lot of things to cook, you have to buy a lot of things....spices, lots of things. So you go back to the most basic things, the things you already know but you don’t have a lot of variety of spices or vegetables.*
CHAPTER V

CONCLUSION

Feasibility of the Diabetes Prevention Program (DPP) T2 Research Study

The findings of this intervention suggests that implementing a modified version of the DPP lifestyle intervention into an low-income assisted living facility was feasible for elderly Hispanic individuals with and at risk for type 2 diabetes. While none of the participants in this study achieved the recommended weight loss goal of 5-7%, which is the gold standard for diabetes prevention, our focus group data suggests that a greater amount of sessions and more provider support were likely needed to achieve this goal. This study demonstrates numerous strengths in that it was culturally sensitive and was reinforced by incorporating behavioral strategies derived from Social Cognitive Theory, however it lacked many known fundamental key elements required to initiate weight loss and sustain weight loss over time. Overall, this intervention was well received by participants, but a longer intervention was needed.

Qualitative Assessment

Few DPP translation studies have conducted qualitative assessments. Our study utilized a post-intervention focus group methodology to gain an understanding of participant opinions regarding the intervention and study curriculum and to evaluate the effectiveness of the intervention. Overall, participants seemed to grasp the concept of diet and exercise in relation to diabetes prevention and management. Portion sizes seemed to be the most beneficial educational component in the curriculum. A major finding was that participants did not feel eight sessions was long enough and requested for the intervention to continue. This finding was different from Davis-Smith (2007) and Mau et
al. (2010). Davis-Smith (2007) selected six of the 16 DPP sessions based on pre-intervention focus group data and held the intervention and follow-up sessions on Saturday mornings based on participant feedback (Davis-Smith, 2007). Similarly, Mau et al. (2010) chose 8 lessons from the 16 DPP sessions based on pre-intervention feedback from participants (Mau et al., 2010). Rosal, Borg, Bodenlos, Tellez, & Ockene (2012), investigated other areas of interest such as knowledge gaps and attitudes pertaining to diabetes prevention, and specific weight loss challenges faced by a low-income Latino community in Lawrence, Massachusetts (Rosal et al. 2012). Pagato et al. (2008) administered an anonymous satisfaction survey and found that while participants were highly satisfied with the intervention, only 56% were satisfied with their weight loss. Overall, qualitative assessment data on DPP translation studies is limited. Focus groups can offer benefits on how to adapt DPP protocols and curriculums according to participants' needs. More in-depth assessments should focus on the knowledge, attitudes and expectations of participants.

**Demographics**

This study was able to reach a low-income elderly Hispanic group in Los Angeles County. Despite the numerous DPP translation studies that have developed innovative and effective approaches to implementing the DPP into real-world settings, minority groups have been underrepresented in these studies (Ockene et al., 2012; Ruggiero et al., 2012). Currently, DPP translation studies have primarily recruited homogeneous samples, which have tended to be Caucasian, middle aged, and primarily women. Through network support, and D&I and diffusion efforts (e.g. the CDC led DPP initiative), the DPP will most likely become available to more diverse populations. However, like the
present study, the few translation studies that have solely targeted Hispanic groups have resulted in modest weight loss (Ockene et al., 2012; Ruggiero et al., 2012) compared to studies where recruitment samples were predominately Caucasian (Ackermann et al., 2008; Seidel et al., 2008). Therefore, to ensure that behavioral based lifestyle interventions reach individuals and populations that suffer from diabetic related health disparities, further DPP translation research efforts are needed to understand how to effectively target and deliver evidence-based interventions to minority groups.

**Older Adult/Elderly Participants**

Despite the null effect metformin had on the incidence of diabetes in older adult DPP participants, few DPP translation studies have strictly targeted this age group. Based on the findings of the original DPP, behavioral lifestyle interventions may offer an opportunity to prevent DM in the older adult population compared to medication alone (Knowler et al., 2002). Our study recognized the importance of targeting elderly individuals at risk for DM since the window of opportunity for prevention is narrower (Centers for Disease Control, 2010). Aside from West et al. (2011), our study was one of the few with an inclusion criterion of greater or equal to 60 years of age. Like West et al. (2011), we also included individuals with type 2 diabetes. While none of the participants in our study reached the 5 -7% weight loss goal, West et al. (2011) found that older adult participants were able to achieve a 3.8% mean weight loss at 4 months after a 12 session intervention. Studies that have included elderly participants, but have not been limited to this age category, have found both advantages and disadvantages to elderly participants meeting intervention goals. In a study conducted by Amundson et al. (2009), participants 60 years of age or older (without hypertension) were 50% more likely to reach the 7%
weight loss goal compared to participants younger than 60 years of age (Amundson et al., 2009). In addition, older participants were more likely to turn in self-monitoring fat tracking records compared to their younger counterparts (Amundson et al., 2009). In contrast, Seidel et al. (2008) found that significantly older individuals were less likely to complete the study intervention (mean age not reported). Although, few translation studies have targeted older adult populations or assessed outcomes within this age group, these studies have demonstrated that older adults may have increased motivation to lose weight compared to their younger counterparts, given age related health issues do not hinder their ability to engage in nutrition and physical activity interventions (Amundson et al., 2009; West et al., 2011). Based off of our focus group data, our study found that older adult participants were motivated to meet study goals, however based on the facilitators observations, participants who suffered from multiple comorbidities associated with type 2 diabetes were not able to engage in the recommended physical activity guidelines, and this was not necessarily related to the age of our participants (age ranged from 61-84 years). Regardless of age, comorbidities have shown to interfere with weight loss goals (Pagato et al., 2008). The issue of comorbidities in relation to weight loss will be further discussed in the limitations section below.

**Setting**

Despite the lack of diversity in participant recruitment, DPP translation studies have expanded to a variety of different settings. In the clinical setting, the DPP has been implemented in primary care centers (Mayer-Davis, 2007) and community based hospitals (Seidel et al., 2008). Translation studies implemented into community settings have been much more varied and have been extended to churches (Boltri et al. 2008), the
workplace (Barham et al., 2011), cardiac rehabilitation centers (McBride et al., 2008) to rural senior centers (West et al., 2011) and even to “frontier” counties in remote areas of Montana (Vadheim et al., 2010). This is the first DPP adapted translation study that has been implemented in a senior living facility in Los Angeles County. This particular setting not only provides an opportunity to reach a diverse group, but offers a cost-effective approach by reducing indirect medical costs associated with participant travel time. In a three-year cost analysis conducted by the Diabetes Prevention Research Group, it was assumed that participants traveled on average 30 minutes to and from their DPP appointments (Herman et al., 2003). Participant travel time (30min) plus time spent at each DPP session was estimated at $8.00 per hour, which was half of the minimum wage in the year 2000. Estimates for travel time alone are not available in the analysis, but considering participants did not travel to DPP group sessions suggests that travel expenses (gas, car maintenance, and time) were spared. The elimination of travel time, may also improve participation rates as well as attendance and attrition, however this was not assessed in this study. In addition, the facility did not charge for the space used to conduct the intervention and the Spanish translation services provided by the Social Service Coordinators, were other cost saving factors in this study. Overall, further studies in this particular setting and/or other living facilities may provide for an ample environment to reach an underrepresented group at risk for diabetes and disease related complications, as well as aid in a successful cost-effective dissemination and implementation process once an adapted DPP model is established.
Facilitator Delivery Modes

This study was facilitated by a registered dietitian and translated to Spanish by social service coordinators. The inclusion of additional staff to help facilitate the intervention would have helped in the assessment of self-management compliance and goal setting/problem solving as well as outcome measures such as weight, body fat, physical activity questionnaires and capillary blood glucose monitoring. However, hiring health care specialists’ are costly and alternative modes of delivery are necessary for intensive behavioral lifestyle interventions to be sustainable in real world settings. To reduce costs associated with hiring health care providers, numerous DPP translation studies have explored the use of paraprofessionals to facilitate DPP interventions (Ackermann et al. 2008, Katula et al., 2011; Wadden et al.,2011). Ackermann et al. (2008) successfully trained YMCA staff to deliver a modified DPP, which resulted in weight loss that was comparable to the DPP. West et al. (2011) was also able to successfully train lay health educators to deliver the DPP to an older adult population (≥60 years of age). In addition, Katula et al. (2011) was able to lead a randomized control intervention by training community health workers (CHW) who had a history of well-controlled type 2 diabetes (Katula et al. 2011). Ruggiero et al. (2011) also used CHW to deliver a modified DPP intervention, however mean weight loss fell to 2.79lbs at the 12 month follow up. Despite an efficacious intervention, Wadden et al. (2011) discussed that the use of specialized personnel (e.g., registered dietitians) rather than medical assistants (MA’s) as well as more intensive coaching (greater than one session per month for the first 3 months) may have resulted in greater weight loss (Wadden et al., 2011). Similar to
our study, Ockene et al. (2011) used health specialists (nutritionist and psychologist) to deliver the DPP, and the intervention resulted in only modest weight loss.

There are numerous potential factors that hinder the efficacy of DPP translation research. It is unclear as to whether health care professionals are able to deliver more effective interventions, as numerous translation studies have been successful in training paraprofessionals to deliver the DPP. Our study however, found that despite help from social service coordinators who were primarily involved with Spanish translation, one health care professional was not sufficient to maintain the fidelity of the original DPP. The use of a registered dietitian was helpful in that limited training was needed to implement the study, however limited staffing was the primary reason as to why the dose and duration, self-management assessments and outcome measures fell short. Considering this study occurred through an established community partnership between TELACU and California State Polytechnic University, Pomona, future studies may consider the use of undergraduate or graduate nutrition students to aid in the delivery of this intensive based program. Alternative modes of delivery such as implementing the DPP through a DVD format with in person monitoring/follow-up may also provide for an efficient yet effective intervention (Kramer et al., 2010).

Cost-Effectiveness

The approximated cost for this intervention was $1,100.00, which totaled to $70.00 per participant. Our costs were reduced by obtaining volunteer services from the facilitator (registered dietitian), Spanish translators (social services coordinators), and the registered nurse who tested blood sugar, as well as the facility space donated by TELACU. Study costs were directly related to materials only (i.e. blood sugar monitors,
handouts, food, supplies and incentives). This cost was similar to another translation study held in a donated church facility ($1075.09), which also only paid for materials (e.g. handouts, food, scales, supplies) (Davis-Smith, 2007). As mentioned prior, behavioral experts e.g., psychologists and registered dietitians, accounted for 54% of the original DPP costs ($750.00 of $1399.00) in the first year alone and are typically compensated at a rate of approximately $30.00 per hour (Herman et al, 2003). Facilitators and facilities who volunteer their time and space will allow for further research to take place in the area of diabetes prevention and management. This will provide the opportunity to identify an effective and sustainable implementation and dissemination strategy and model needed in this population group.

**Study Limitations**

**Study Design & Participants**

This study had several limitations. This study was tested in only 2 TELACU living facilities and there was no control group. Furthermore, this study had a small sample size, and consisted of primarily women. The original goal of the study was to recruit elderly individual at risk for diabetes, however 47% of participants who wanted to join the study had previously been diagnosed with type 2 diabetes. If more men and at risk individuals are to join future DPP translation studies, alternative methods of screening and recruitment are needed.

**Efficacy**

Although mean percent weight loss only resulted in a 1.56% decrease at 12 weeks, the total mean weight loss achieved by participants reached a significant difference from baseline to completion of the study. At 12 weeks, there were significant
reductions in mean weight (2.63 lbs, P<.002) compared with baseline, and this was associated with a decrease in BMI (0.51kg/m; p<.001). In terms of weight loss, the results of this study were similar to Ockene and colleagues (2012), which resulted in a 2.5lb. weight loss after implementing a 16 session intervention carried out over 1 year (Ockene et al., 2012). Our study however, was not designed or intended for efficacy, but implemented to evaluate the feasibility of a modified version of the DPP, to target an underrepresented age and ethnic group at risk for diabetes and diabetes complications, and to evaluate whether residents in this setting were receptive to a behavioral lifestyle change intervention. The weight loss achieved in this study was an expected result and likely caused by several factors that can be improved upon given this study design be implemented in this particular setting and group again in the future.

**Dose & Duration**

The dose and duration of the intervention was a major contributing factor to the lack of weight loss achieved in this study. Dose is referred to how many contacts participants receive throughout the study and duration is based on how long an intervention is carried out. In the DPP for example, a total of 16 contacts (16 individualized sessions) plus physical activity sessions (2 times per week) were offered in the first six months of the program, and 12 contacts (4 in person and 4 phone) were offered between 7-12 months of the program. In the maintenance phase (Phase 2), contacts were offered one time per month for two years. The DPP was designed to ensure that the appropriate dose and duration was sufficient to produce clinically significant weight loss of 5-7%, as this is the known weight loss recommendation for clinical efficacy trials (Vendetti & Kramer, 2012; Wing, Tate, Gorin, Raynor, & Fava, 2006).
Based on reviewing DPP translation study outcomes, Venditti & Kramer (2012), suggest that a minimum of 4 to 6 months of weekly contacts are needed to induce weight loss and frequent follow-up contacts are needed for a least one year to maintain weight loss (Venditti & Kramer, 2012).

Most translation studies have reduced the dose and duration of the original DPP to evaluate cost-effectiveness in relation to efficacy. From our knowledge, a total of six sessions (no maintenance phase) was the lowest dose and duration of all DPP translation studies to date, which resulted in a mean weight loss of 8.8-, 6.5-, and 10.6lb weight loss at 6 weeks (immediately after the intervention), and at the 6 and 12 months follow-up (Davis-Smith, 2007). Cramer et al. (2007) reported a slightly lower mean weight loss of 5.4 lbs (2.49%) at 8 months after implementing a 7-session (one time per month with phone calls two times per week) intervention (Cramer et al., 2007). Our study implemented an 8 session (one time per week) intervention with no maintenance contacts, which resulted in a 2.63lb wt loss (1.56%) at 12 weeks, and did not assess this measure at 6, 8, or 12 months.

The appropriate dose and duration is critical in preventing weight regain after successful short-term weight loss is established (Venditti & Kramer, 2012). Numerous DPP translation studies that have demonstrated significant reductions in short-term weight loss have found that weight regain occurs at the follow-up measure despite offering maintenance contacts. For example, Ruggiero et al. (2011) discovered a weight regain of 2.73lbs at the 12 month follow up measure. Jiang et al. (2013) found that the initial mean weight loss of 9.6lbs decreased to 5.6-, 3.1-, and 2.4lbs annually over a three year study period. In contrast, Vadheim et al. (2010) found weight loss continued from
7.5kg (after 16 sessions 1time per week) to 8.7kg (after 6 monthly maintenance sessions). This study differed from the original DPP in that it offered 16 weekly contacts over 16 weeks rather than 16 contacts over 16-24 weeks and only offered 6 monthly contacts rather than 8 contacts over six months. With few exceptions, one short-term study (six sessions and no maintenance contacts) found that weight loss continue from six weeks to (8.8lbs) to the 12month follow-up (10.6lbs). This mostly likely occurred due to the involvement of community efforts in a church based setting, which offered recognition to individuals who were making lifestyle changes as well as the concerted effort to offer healthier menu options and physical activity sessions at the church (Davis-Smith, 2007). Our study observed that individuals who developed partnerships during walking exercises were more likely to meet weekly exercise goals and should be encouraged in future studies.

It is clear that the appropriate dose and duration is needed to induce clinically significant weight loss of 5 to 7% as this intensity may be needed to maintain motivation and offer much needed support to individuals aiming to make lifestyle changes and reach short-term as well as long-term program goals. As mentioned prior, our focus group data suggests that participants wanted longer amount of sessions to stay motivated in pursing the weight loss study goals. The inclusion of a longer amount of sessions was identified as necessary for future interventions in terms of accomplishing goals and achieving long-term success. This was an unexpected finding as it indicates that participants valued the intervention, however it also solidifies the known factor that dose and duration were not sufficient in this study. The 12-session Group Lifestyle Balance (GLB) program, which is a streamlined version of the original 16-session DPP, may be better suited for this setting
and group. West et al. (2011) found that 73% of elderly participants found the number of sessions in the GLB to be “just right,” however it is unknown if participants who were not satisfied would have preferred longer or shorter amount of sessions (West et al., 2011). From a public health standpoint, it is imperative that future studies strive to implement the appropriate amount of sessions (dose) for the appropriate length of time (duration) to truly meet the needs of individuals who are investing their time and efforts into reaching health goals that are essentially proposed by the health care provider. Further diabetes management and prevention interventions offered to this group in this particular setting should ensure that this level of care is provided.

**Comorbidities**

As part of the TELACU assisted living etiquette policy, study facilitators or activity leaders, cannot deny residence access to a study/activity if they wish to participate. This study was initially intended to recruited elderly Hispanics with prediabetes, however the majority of individuals who wished to join were either previously diagnosed with type 2 diabetes or overweight (BMI of >25 kg/m²), and therefore the study inclusion was reevaluated and opened to these individuals. The DPP clinical trial and the majority of translation studies have not included individuals diagnosed with type 2 diabetes as the primary goal of these studies were diabetes prevention rather than diabetes treatment. As experienced in this study, the inclusion of type 2 diabetes presents numerous challenges to reaching weight loss goals and introduces the issue of balancing weight loss with blood sugar management.

Individuals with type 2 diabetes are more likely to have existing comorbidities, e.g. hypertension, CVD, depression, and microvascular disease, which can present
barriers to reaching weight loss and physical activity goals (Pagato et al., 2008). Pagato et al. (2008) reported that individuals with comorbidities (21% had type 2 diabetes) had (3.87lbs) less weight loss compared to participants without comorbidities (p<.05). In contrast, McBride et al. (2008) included individuals with type 2 diabetes, and did not experience this barrier; however these individuals had a recent diagnosis of six months or less. The duration of diabetes most likely has an impact on attained weight loss. In a DPP translation study conducted by Mayer-Davis (2007), the inclusion of participants was limited to individuals with type 2 diabetes with a mean age of 45 years or older (mean age = 59.7 years). At six months, the intervention group had a “modest” mean weight loss of 5.72lbs (percent not reported), after 16 sessions (one time per week), and maintenance contacts were given for up to six months. The duration of diabetes for this group was 8.4 years, which was thought to be a barrier to weight loss (Mayer-Davis, 2004). In our study, the mean weight loss was 2.63 lbs. at 12 weeks (8 sessions offered) and the duration of diabetes was most likely longer due to the age of our participants (mean age 72.1 years).

The Action for Health in Diabetes (Look Ahead) clinical trial protocol, which was published after this study, may offer insights into how to offer behavioral lifestyle interventions to individuals with type 2 diabetes (Wing et al. 2013). However this protocol, which was based on the DPP curriculum, was even more intensive than the original DPP, and subjects in the intervention group were younger (mean age= 58.6±6.8) and the mean duration of diabetes was only 5 years (Wing et al., 2013). In addition, this study did not result in improvements in low-density lipoprotein (LDL) cholesterol levels and unfortunately cardiovascular morbidity and mortality differences were not found.
between the two groups despite percent weight loss being greater in the intervention group (6%) compared to the control (3.5%) at the 10 year follow-up. Wing et al. (2013) suggested a possible greater weight loss was needed to reduce cardiovascular related complications, and also suggested exploring other dietary avenues such as the Mediterranean diet rather than focusing solely on reducing fat and calories as recommended in the DPP protocol. Focusing on reducing and monitoring sugar intake may also be a necessary dietary component to add to intensive behavioral lifestyle interventions to prevent increases in LDL-cholesterol. In a recent National Health and Nutrition Examination Survey (NHANES -1999-2006), LDL-cholesterol trends significantly increased (P=.047 for linear trend) as sugar consumption reached greater than 25%. However, this finding was only observed in women, but not in men (Welsh et al., 2010). Nonetheless, recommending a daily sugar gram intake as well as fat intake is something to consider for future studies.

At the present time, more research is needed to understand how elderly individuals with longstanding type 2 diabetes and other existing comorbidities can benefit from intensive behavioral lifestyle interventions. DPP translation studies involving individuals with type 2 diabetes most likely need tailored treatments that address weight loss through diet and exercise, as well as careful monitoring and education on blood glucose control. To our knowledge, this is one of the first DPP translation studies to incorporate a blood sugar management component into the DPP curriculum. However, due to limited data changes in blood sugar were not assessed.
Recruitment & Screening

Our study had difficulties recruiting individuals at risk for diabetes. The majority of participants who joined the study were previously diagnosed with type 2 diabetes. Older age is an increased risk factor for type 2 diabetes, so it is unknown if prediabetes is actually prevalent among elderly individuals residing at the TELACU living facilities. It is also unknown if individuals who have prediabetes have not been diagnosed and therefore did not feel the study was relevant to them. Discovering new ways to improve the recruitment process is essential for individuals to benefit from diabetes management and prevention interventions. Our recruitment method used flyers and word of mouth to inform residents about the study intervention. While this was a simplistic and fairly effective approach, gaining support from local physicians offices where residents obtain the majority of their care may provide another avenue of recruitment. Developing partnerships with local doctors who are willing to screen and refer at risk individuals to a DPP or diabetes management based program may possibly increase the number of participants who would join an intervention. Physician support could also allow access to laboratory data that are often difficult to obtain. Several DPP translation studies conducted in the primary care settings have found that the involvement of physicians helps strengthen weight loss support and the ability to gather outcome measures (Wadden et al., 2011).

Safety & Adverse Events

The inclusion of individuals with type 2 diabetes introduced the potential risk for adverse effects related to hypoglycemia, however no adverse events were reported during the study period. Our study population was at increased risk for hypoglycemia due to
their advanced age, use of insulin (secretagogues), and longer duration of the disease (Amiel, Dixon, Mann, & Jameson, 2008). Due to this risk factor, the facilitator incorporated an educational session on hypoglycemia during session 2, “Being Active a Way of Life.” There is concern about how to prioritize glycemic control and weight loss in individuals with type 2 diabetes due to hypoglycemia (Schwartz & Kohl, 2010). Both type 2 diabetes and overweight are independent risk factors for CVD (Eeg-Olofsson et al., 2009), and therefore balancing glucose control (hyperglycemia and hypoglycemia) with weight loss and correcting CVD risk factors (blood pressure, low HDL, high LDL) are critical for effectively managing patients with type 2 diabetes (Schwartz & Kohl, 2010). DPP translation studies that have included older adults with type 2 diabetes have not discussed how hypoglycemic management was achieved (West et al., 2011; McTigue et al., 2009; Pagato et al., 2008), however our study found that more intensive monitoring of glycemic control was needed to understand how to prioritize and balance weight loss and blood glucose recommendations. Throughout the study, the facilitator continuously informed participants to discuss weight loss and glycemic control with their medical doctors, however as mentioned prior an integrative approach with participants’ primary care physicians as well as additional staff members to help monitor self-management outcomes, most likely would have provided for a more effective management team as well as a safer environment for this study group. Recruiting only individuals at risk for diabetes would eliminate this safety concern, however the benefits of intensive behavioral lifestyle interventions for individuals with type 2 diabetes is important, and shown to be generally safe and feasible in this study group.
Program Adherence through Self-Monitoring

Unfortunately, due to staffing limitations, this study was unable to monitor and evaluate participants’ self-management behaviors on a consistent basis. Participants in this study were provided with self-monitoring tracking forms at the end of each session and encouraged to track fat grams and physical activity on a daily basis as well as other areas that pertained to session topics e.g., sugar and fiber intake. However, tracking forms were only reviewed by the study facilitator at the request of participants, which typically occurred at the end of the study sessions when participants approached the study facilitator with questions. At each weigh in (baseline, 4, 8, and 12 weeks) weight loss goals were discussed and reinforcement of self-monitoring practices were encouraged, but this was the extent of support offered in this area.

The importance of self-monitoring in achieving weight loss cannot be understated. There is strong evidence suggesting that the use of self-monitoring strategies is an effective behavioral strategy to achieving sustainable weight loss (United States Department of Agriculture, 2012). For diabetes, self-monitoring is critical in blood sugar regulation and is associated with lower HgA1C levels (American Diabetes Association, 2013). The original DPP protocol incorporated behavioral strategies such as self-monitoring, problem solving, stimulus control and goal setting into the curriculum, which was evaluated by study counselors at each individual contact session (16 individual contacts in the first 6 months and 8 contacts from 7-12 months). Monitoring and evaluating self-management adherence and offering support where needed is critical in achieving weight loss. Several DPP translation studies which investigated the association between self-monitoring and weight loss, have found that self-monitoring is associated
with greater weight loss. Amundson et al. (2009) reported that participants who self-monitored fat intake more frequently had a greater weight loss (Amundson et al., 2009). More specifically, West et al. (2011) found that participants who submitted ≥50% of their self-monitoring tracking book had 7.6 times higher odds of losing ≥5% at 4 months compared to participants who submitted less than 50% of their tracking information (West et al., 2011). This indicates that encouragement of self-monitoring alone is not sufficient to reach weight loss goals. Individuals must be held accountable for following program guidelines and facilitators must monitor and review self-monitoring tracking forms to ensure that individuals are meeting program goals and to address barriers when needed.

**Physical Activity and Weight loss**

The original DPP offered supervised physical activity sessions twice per week during the first six months of the program. Due to limited staffing, this study held one supervised physical activity session, which was delivered by a certified personal trainer. Participants were provided with a detailed handout displaying a series of pictures based on the demonstrated exercises taught in the physical activity session. Participants were encouraged to practice these exercises in conjunction with moderately intensive walking to meet the exercise goal of greater or equal to 150 minutes per week. As mentioned prior, self-monitoring of physical activity was not monitored or assessed by the facilitator and therefore, it is unknown whether participants met physical activity goals. Physical activity goals however, were reviewed and discussed with participants during each weigh in at baseline, 4, 8, and 12 weeks. The importance of monitoring physical activity levels cannot be understated since numerous studies have found a direct correlation between
physical activity and weight loss (Wing et al. 2004; Pinelli, Brown, Herman, & Jaber, 2011). In addition, Ockene et al. (2011), reported that a modest mean weight loss (2.5lbs.) was attributed in part to the fact that no changes in physical activity were found among participants (Ockene et al., 2011). Our study resulted in a mean weight loss of 2.63lbs, which suggests that physical activity goals were most likely not met by at least some of our participants. Based on facilitator observations, physical activity questionnaire reviews, and verbal communication with participants, those who established a walking partner or joined Curves for example, were those participants who reached a 5lb or greater weight loss from baseline to 12 weeks. Offering supervised physical activity sessions may have affected the degree of change in physical activity and weight loss among participants and is recommended for future studies to improve weight loss outcomes.

Our study initially planned to assess the association between changes in physical activity and weight loss over the course of the study. We chose the Women’s Health Initiative Physical Activity Questionnaire (WHI PAQ) because it has demonstrated validity in an older adult population (Meyer, Evenson, Morimoto, Siscovick, & White, 2009), however due to incomplete data at week 8 and 12, we were unable to statistically analyze changes in physical activity levels. Despite participants receiving guidance on how to fill out the WHI PAQ’s from the social service coordinators (SSC’s) at baseline and week 4, participants were unable to thoroughly complete the forms at week 8 and 12. Although, the Women’s Health Initiative Physical Activity Questionnaire was designed for an elderly population, this particular questionnaire may have been too comprehensive for this study group. Assessing the number of steps based on pedometer readings and or
finding a more simplistic physical activity questionnaire to assess changes in physical activity may provide for a more effective assessment tool and is recommended for future studies.

**Attendance**

Overall attendance was fairly good throughout the entire intervention. Out of 15 participants, a total of 11 to 14 participants were present at all times during the 8 sessions offered. However, based on translational research findings, missing sessions have shown to result in differences in body weight as well as incidences of diabetes. Mau et al. (2010) found that mean weight loss was significantly greater among participants who completed all 8 sessions (1.8 kg, 95%CI) compared to those who completed less than 8 sessions (0.70 kg, 95%CI) (Mau et. al, 2010). In terms of incidence of diabetes, Jiang et al. (2013) found that the cumulative incidence of diabetes was significantly lower among participants who attended all 16 sessions compared to participants who attended 15 sessions or less (P<0.0001). In addition, the crude incidence of diabetes was 4% less for participants who attended all 16 classes, compared to those who did not complete all of the sessions (3.5% vs.7.5) (Jiang et al., 2013). Positive correlations between attendance and body weight have been found in other translations studies as well (Pinelli et al., 2011; Jaber et al., 2011). These findings suggest that higher attendance rates are associated with reductions in weight loss and incidence of diabetes. Like Jiang et al. (2013) our study found that a scheduling conflict interfered with attendance rates. This was particularly notable in the non-consistent attenders group. Considering attendance is critical to the success of intensive behavioral lifestyle interventions, alternative options or make-up sessions may be helpful for participants who absolutely cannot attend sessions, however
the importance of attendance should be discussed with participants prior to the intervention. In addition, to maximize the chances of successful attendance rates, a pre-intervention qualitative assessment (focus group) may offer data on the best day and time to offer the intervention.

**Summary**

In summary, this modified DPP intervention developed and evaluated a culturally sensitive curriculum derived from social cognitive theory, which was tested in an elderly Hispanic +population. Due to the inclusion of individuals with type 2 diabetes, a blood sugar management education component was incorporated into the adapted DPP curriculum. This lifestyle intervention produced a modest, but significant improvement in weight at 12-weeks. The intervention was well received by participants. However, the focus group data indicated a participant need for a longer intervention. Implementation of this intervention in communities living facilities offer cost benefits, but should be implemented with the sufficient dose and duration needed to produce clinically significant weight loss.
REFERENCES


important strategy to address health care disparities. *Health Affairs, 24*(2), 499-505.


151
Uusitupa, M., Peltonen, M., Lindstrom, J., Aunola, S., llanne-Parikka, P.,
Kinaned-Kluaanniemi, S.,…Tuomilehto, J. (2009). Ten-year mortality and
cardiovascular morbidity in the Finnish diabetes prevention study: Secondary
Vadheim, L.M., Brewer, K.A., Kassner, D.R., Vanderwood, K.K., Hall, T.O., Butcher,
M.K.,…Harwell, T.S. (2010). Effectiveness of a lifestyle intervention program
among persons at high risk for cardiovascular disease and diabetes in a rural
Vadheim, L.M., Brewer, K.A., Kassner, D.R., Vanderwood, K.K., Hall, T.O., Butcher,
intervention can be effectively delivered through telehealth. Diabetes Educ,
36(4), 651-656.
cardiovascular disease and diabetes prevention program. Diabetes Care, 33(12),
2543-2545.
interventions to reduce diabetes risk. Curr Diab Rep, 12, 138-146.
community-based, culturally tailored diabetes prevention intervention for high-
risk adults of Mexican descent. The Diabetes EDUCATOR, 40(2), 202-213.
Wadden, T.A., Volger, S., Sarwer, D.B., Vetter, M.L., Tsai, A.G., Berkowitz,
R.I.,…Moore, R.H. (2011). A two-year randomized trial of obesity treatment in


