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A Comparison of the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults to Clinical Outcomes of a PLMM Intervention among Hispanics

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ABSTRACT

Obesity is a serious and costly condition, causing a higher prevalence of chronic diseases and having an average medical cost of $1,430 higher than non-overweight patients (Finkelstein, Trogdon, Cohen, & Dietz, 2009). With more than two thirds of U.S. adults suffering from overweight or obesity, health organizations have recognized the disease as a threat to the well-being of the nation. In 2013, the American Health Association (AHA) and the American College of Cardiology (ACC) among other stakeholders developed a set of guidelines and recommendations for primary health providers in order to reduce overweight, obesity and concomitant conditions (Jensen et al., 2014). The evidence-based guidelines suggest the elements of weight loss lifestyle interventions that have been proven to result in clinically meaningful health benefits for patients. Nevertheless, the guidelines also report the gaps in evidence, such as the need to understand and improve the efficiency of on-site lifestyle interventions on key populations including racial/ethnic groups.

The overall goal of this study was to assess weight and blood pressure changes of Hispanic adult participants who engaged in a Promotora-Led Mi Corazon Mi Comunidad (PLMM) intervention. A total of 753 participants were initially enrolled in the intervention conducted from 2009 – 2013 in El Paso, Texas. The 2013 AHA/ACC/TOS Guideline was used as a reference to assess weight and blood pressure changes between pre- and post-intervention. The specific aims of the study were: 1) to identify participants who upon enrollment met 2013 AHA/ACC/TOS Guideline cut-off points for overweight and obesity; 2) to identify participants who in addition to meeting the overweight and obesity criteria, also met the cut-off points for waist circumference in the 2013 AHA/ACC/TOS Guideline (n=500); 3) to determine the proportion of female and male participants who achieved 3, 5 and 10 percent weight reduction

milestones consistent with recommendations from the 2013 AHA/ACC/TOS Guideline after the 4-month intervention, and 4) to determine blood pressure changes in female and male participants who completed the PLMM intervention (n=285).

Results from secondary data analyses indicated that 57% of eligible participants were retained after the 4-month intervention. The 285 participants that completed the intervention achieved an average weight loss of 1.48% ±3.33. The median weight loss of 1.31±3.3 kg was statistically significant (p=0.001), which represents a 0.5±1.29 kg/m^2 (p=0.001) decrease in overall BMI measurements. In addition, there was a statistically significant reduction of 3.32 ± 6.38 cm (p=0.001) in waist circumference, a measurement strongly associated with cardiovascular health risk. Diastolic and systolic blood pressure were also reduced by 0.59 and 0.84 mmHg respectively among the selected sample of participants. A total of 28% of the 285 selected participants that completed the PLMM achieved a body weight loss of 3% or more, which according to the 2013 AHA/ACC/TOS Guideline will produce clinically meaningful health benefits.

In conclusion, the 4-month intervention led by Community Health Workers/Promotores de Salud proved to be an efficient method to reduce overweight and obesity among Hispanic adults living in El Paso, TX. The inclusion of an individualized diet component and increase in the intervention time to 6 months or more could further improve the health benefits achieved by the PLMM intervention

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INTRODUCTION

Obesity is considered one of the top three most urgent health concerns in the United States (U.S.) (Gallup poll, 2014). The prevalence of overweight and obesity has been progressively rising over the last 40 years and is currently at unprecedented levels, when combined, more than 68.0% of US adults are considered above normal weight and 33.8% are obese (Flegal, Carroll, Ogden, & Curtin, 2010). There are significant economic costs associated with obesity. According to Finkelstein et al., in 2010 the total medical cost of obesity, now considered a disease, was approximately 73.1 billion dollars. Medical and health care communities consider obesity as a multifactorial disorder caused by various contributing factors such as genetics, environment, and lifestyle. Therefore, a comprehensive lifestyle intervention comprised of physical activity, diet and behavioral therapy has a higher possibility to succeed in promoting and maintaining weight loss (Pagoto & Appelhans, 2013). Comprehensive lifestyle interventions are important tools to address disparities in the prevalence of overweight and obesity in the population. For instance, when compared to the US population individuals from Hispanic descent are disproportionately affected by overweight and obesity. In 2013, the American Heart Association (AHA), American College of Cardiology (ACC) and The Obesity Society (TOS) developed a set of guidelines and recommendations based on high quality randomized trials, meta-analyses and observational studies (Jensen et al., 2013). There is a lack of information about obesity lifestyle interventions for Hispanics living in the U.S.-Mexico border incorporating the 2013 AHA/ACC/TOS overweight and obesity guideline. The 2013 AHA/ACC/TOS Guidelines recognized that research is needed to better understand and improve the efficiency of on-site lifestyle interventions on key populations including racial/ethnic groups.

The objective of this study was to conduct a secondary data analysis from the cross-sectional data collected in the Promotora-Led Mi Corazón Mi Comunidad Intervention (here on forward PLMM) implemented in Hispanic adults from 2009 to 2013 living in El Paso, Texas that compared its clinical outcomes to the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. The PLMM intervention was implemented in less time than what the 2013 AHA/ACC/TOS guidelines recommend. However, the intervention applied a high number of physical activity sessions and nutrition education and was implemented by Community Health Workers (CHW)/Promotores de Salud (PS). This study only evaluated the clinical outcomes of overweight and obese participants and identified those who achieved the recommended 3-5% weight loss according to the 2013 AHA/ACC/TOS Guideline after the intervention was completed. The study also evaluated the effectiveness of CHW/PS to deliver weight loss lifestyle interventions to Hispanic community. Potential results from this study are stated as gaps of evidence and future research essentials in the 2013 AHA/ACC/TOS Guidelines. The guidelines recognized the need for studies focusing on improvements in efficacy, optimizing dissemination and targeting special populations. The 2013 report emphasizes that further research is needed to better understand and improve the efficiency of on-site lifestyle interventions (14 or more contact sessions) on key populations including racial/ethnic groups (Jensen et al., 2013). Furthermore, the gaps in evidence require studies that can be delivered in the community as opposed to academic settings and to determine the adequate skills and personal characteristics required to serve in lifestyle interventions.

CHAPTER 1: BACKGROUND AND SIGNIFICANCE

1.1 Overweight and Obesity

Overweight and obesity are serious conditions defined as excessive fat accumulation in the adipose tissue that is adversely associated with health. This abnormal fat accumulation in humans is considered a complex disorder caused by hereditary and environmental factors that disturb the energy balance (Buttar, Li, & Ravi, 2005). This unbalance is usually caused by a high dietary intake that surpasses the energy expenditure. There are highly efficient methods to calculate total body fat such as bioelectrical impedance and dual-energy X-Ray absorptiometry. However, these methods are often expensive and not universally available. In addition, the previously mentioned methods lose accuracy on severely obese individuals. One of the most common measurement that are used internationally to classify overweight and obesity in adults is Body Mass Index (BMI). BMI is calculated using the person's weight [kg] divided by the square of their height [m^2] (Eknoyan, 2008). According to the 1998 Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults (The Evidence Report) and the World Health Organization (WHO), overweight is defined as a condition when people have a BMI equal or greater than 25 kg/m^2 and obesity is consistent with a BMI equal or greater than 30 kg/m^2 (NHLBI, 1998; WHO, 2014c) (Table 3). BMI is a valuable tool for health care practitioners since it is an inexpensive and universally available method that correlates weight with total body fat on a population basis.

1.1.1 Health Consequences Associated with Overweight and Obesity

Overweight and obesity are associated with a higher incidence of cardiovascular disease (CVD), liver disease, dyslipidemia, and certain types of cancer (Mozaffarian et al., 2015). The

harmful health consequences of weight gain extent from non-fatal reduction of quality of life to increased risk of premature death. Obesity is considered a major risk factor for type 2 diabetes given that 80% of patients diagnosed with the disease are overweight or obese (Smyth & Heron, 2006). In addition, in a systematic review of 57 prospective studies, the presence of obesity is directly proportional to risk of death after adjusting for smoking status (Prospective Studies Collaboration, 2009).

The non-fatal health problems associated with obesity include skin problems, respiratory difficulties, infertility and chronic muscular-skeletal problems. Obesity has been recognized as a key risk factor for the development of other chronic and non-communicable diseases. When compared to normal weight adults, obese persons have an overall increased risk of death for all-causes of death, low quality of life, and serious health conditions. The following conditions have been linked to obesity: hypertension, dyslipidemia (high Low-Density Lipoprotein (LDL)-cholesterol and low High-Density Lipoprotein (HDL)-cholesterol, or high levels of triglycerides), type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and breathing problems. In addition, obesity is a risk factor for some cancers (endometrial, breast, colon, kidney, gallbladder, and liver), reproductive hormone abnormalities (polycystic ovary syndrome), mental illness (clinical depression, anxiety, and other mental disorders), body pain, difficulty with physical functioning and low back pain (Mozaffarian et al. 2015; NHLBI, 2013; CDC, 2015; Bhaskaran et al. , 2014). Lastly, it has been reported that individuals with higher BMI independent of age and gender, have a 30% increment rate for all-cause mortality. Increments of 5 kg/m^2 over the normal BMI range (25 kg/m^2) signify additional risk for vascular disease (40%), as well as for diabetes, renal and hepatic disease (60-120%) and other conditions (Prospective Studies Collaboration 2009).

1.1.2 Overweight and Obesity Prevalence

Worldwide, overweight and obesity are recognized as a serious and rapidly growing threat to the health of the world's population. The prevalence of this health condition knows no boundaries, having an impact on developing and developed countries alike. Globally, 39% of adults 18 years or older are overweight while 13% are classified as obese (WHO, 2014). In 2012, more than two-thirds (68.5%) of U.S. adults age 20 and older were considered either overweight or obese (NIH, 2012). Obesity is estimated to affect more than one-third (34.9%) of the adult population with an occurrence of 6.4% for extreme obesity (BMI of 40 or more) (NIH, 2012; Ogden, Carroll, Kit & Flegal, 2014). Among Americans 71.3% of men and 65.8% of women were classified as overweight or obese, while 33.5% of men and 36.1% of women were obese. *The State of Obesity website* (2014) ranks Texas at the 11th place for adult obesity in the U.S. The impact obesity is having on world health has encouraged many researchers and health practitioners to characterize the condition as a disease. Accordingly, in 2008 and 2013, the Obesity Society (Allison et al. 2008) and the American Medical Association (Pollack 2013) respectively, expanded their classification of obesity from being a risk factor to disease. Although this reclassification has no legal authority and is opposed and criticized by many (Katz 2014, Stoner & Cornwall 2014); the objective of these association was to increase awareness, reduce the stigma of obesity and potentially pave the way to facilitate insurance reimbursement for obesity medications, surgery, and counseling (Pollack 2013).

1.1.3 Economic Cost of Overweight and Obesity

The economic impact associated with overweight and obesity for a country is significant. Direct medical cost is represented by the medical diagnosis, prevention, and treatment of obesity;

while indirect costs include economic loss from work absenteeism or decrease in productivity. In 2010 it was estimated that globally, overweight and obesity caused 3.4 million deaths, 3.8% of disability adjusted life years (DALYs) and 3.9% of years of life lost (Ng et al., 2014).

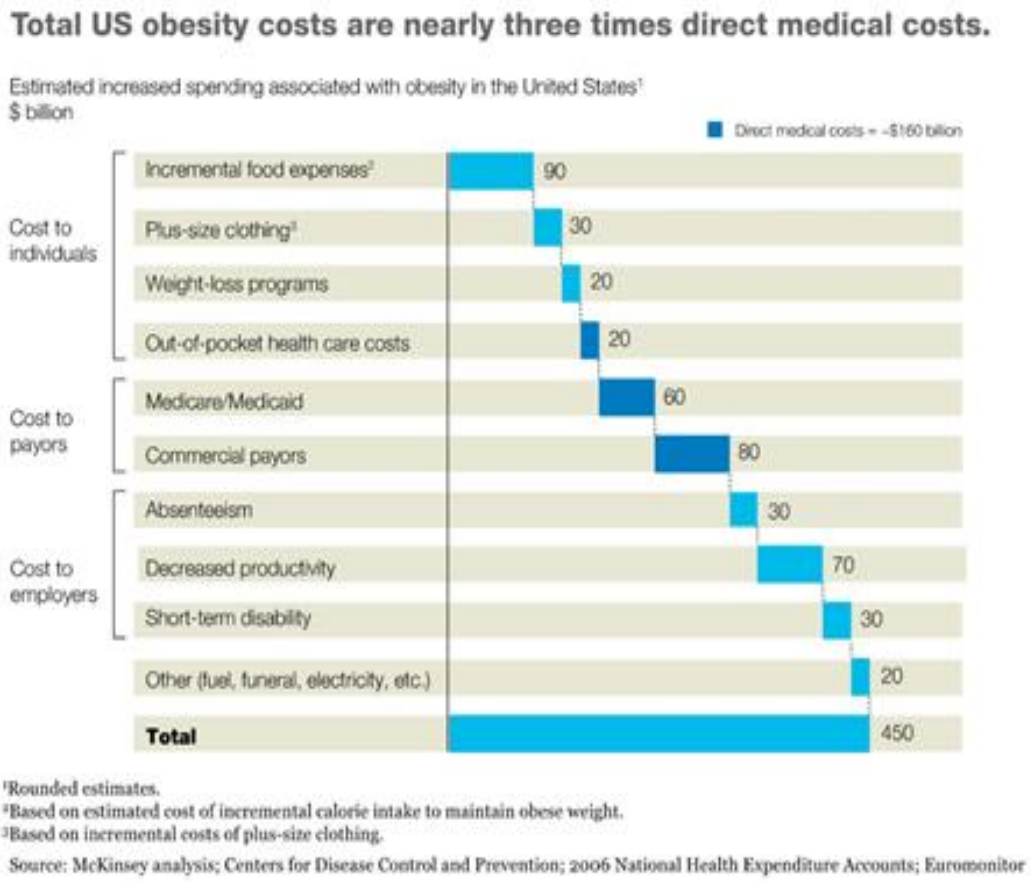

Figure 1. Total U.S. obesity costs (Algazy, Gipstein, Riahi, & Tryon, 2010).

The McKinsey report published in 2010 indicated that 160 billion dollars were spent in direct medical costs associated with obesity in the U.S. (Figure 1). The report estimates that the overall cost of obesity is 450 billion dollars in the U.S. alone (Algazy, Gipstein, Riahi, & Tryon, 2010).

1.1.4 Causes of Overweight and Obesity

The cause for overweight and obesity is more complex than an energy unbalance. Many factors such as environmental, behavioral, and genetic factors as well as medical conditions contribute in varying degrees to overweight and obesity (Aronne, Nelinson, & Lillo, 2009; Faith & Kral, 2006). Behavioral factors (e.g. poor diet, inactive lifestyle, lack of sleep) affects adults and children alike and have become a leading public health concern given that it adds substantially to the burden of chronic health conditions (WHO, 2014b). It has been suggested that factors in the everyday environment promote these behaviors. High calorie processed food products are heavily marketed and readily available in the communities. In addition, these products are consistently cheaper than more nutrient dense foods (Rao, Afshin, Singh, & Mozaffarian, 2013; Andrieu, Darmon & Drewnowski, 2006). Physical activity can help reduce the burden of overweight and obesity as well as many of its associated chronic diseases. However, despite all the health benefits, physical activity levels have been declining worldwide, mostly due to the adoption of sedentary behaviors of modern life such as increased working hours, television watching, internet, video games, etc. (WHO, 2011). Other factors such as socioeconomic status (SES) and education have shown to have an influence on obesity. According to Wang & Beydoun (2007), the SES has an influence on obesity and it varies by ethnicity; however, the ethnic differences in obesity are not fully explained by SES alone. It has been recognized that education plays a role on obesity. In 2007, Wang and Beydoun analyzed the National Health and Nutrition Examination Survey (NHNES) data and reported that the prevalence of obesity is higher among less educated people in the U.S., with the exception of black woman. On the other hand, the Centers for Disease Control and Prevention (CDC) reported no trend between obesity and education among man (Ogden, Lamb, Carroll, & Flegal, 2010).

Interestingly, in the same study, a significant trend shows that educated women are less likely to be obese compared with less educated women (Ogden, Lamb, Carroll, & Flegal, 2010).

1.1.5 Overweight and Obesity among Hispanics

The Hispanic population is the largest minority group in the U.S. and one of its fastest growing ethnic groups. Currently, 17 % of the U.S. population is Hispanic and this number is expected to reach 31% by the year 2060 (Krogstad, & Lopez, 2014). Studies have found racial/ethnic differences in the prevalence of obesity with Hispanics and non-Hispanic blacks having the highest age-adjusted rates when compared to non-Hispanic whites and non-Hispanic Asians (Ogden, Carroll, Kit, & Flegal, 2012). During 2011-2012 it was reported that 42% of Hispanics were obese surpassed only by non-Hispanic blacks with 47.8% while Asians and whites had obesity rates of 10.9 and 33.4 respectively (Ogden, Carroll, Kit, & Flegal, 2012). The prevalence of class 3 obesity followed a similar trend with percentages of 12.1, 5.8, 5.6 and 0.9 for Black, Hispanic, White and Asian respectively (Ogden, Carroll, Kit, & Flegal, 2014). Ogden et al (2014) reported that 16.9% of youth (2 to 19 years old) in the U.S. were obese. Hispanic youth had the highest obesity prevalence with 22.4 % when compared to youth from Asian (8.6%), Black (20.2%) and White (14.1%) ethnicities (Ogden, Carroll, Kit, & Flegal, 2014). The occurrence of obesity among the Hispanic population creates further disparities when associated to chronic diseases; 13.2 % of Hispanics adult are affected by diabetes compared to the 7.6% from the white counterparts. In addition, Hispanics suffer 43% more from stroke than persons from white ethnicity (Schiller, Lucas, Ward, & Peregoy, 2012).

The obesity and overweight disparity among different ethnic groups has been attributed to several causes that contribute to the problem. In the U.S., there is a well-known association

between SES and obesity as previously mentioned varies by ethnicity (Wang & Beydoun, 2007). In the U.S. people with higher SES were less likely to be obese (Wang, 2001; Wang & Beydoun, 2007). The previous statement is true for people of white ethnicity; however, reports have shown that among Hispanic youth there is no significant trend in obesity prevalence by income level (Ogden, Lamb, Carroll & Flegal, 2010). It is worth mentioning that in lower income countries, people with higher SES had higher prevalence for obesity (Dinsa, Goryakin, Fumagalli & Suhrcke, 2012). Accordingly, SES is not the sole reason for the prevalence of obesity in the Hispanic community, but multiple causes contribute to the disparity. Hispanic acculturation and generational status mainly via associations with diet and physical activity have been linked to obesity (Ayala, Baquero, Klinger, 2008). Corral et al. (2014) stated that Hispanic people preferred to live in residential areas that have their same ethnicity. The authors highlighted that these neighborhoods usually have a decreased number of recreational facilities and a higher number of fast food outlets than white neighborhoods with similar SES; thus suggesting that segregated Hispanic neighborhoods promote an environment conducive of obesity (Corral, Landrine & Zhao, 2014).

1.2 Benefits of Weight Loss

The adverse effects of overweight and obesity are evident given their strong association with chronic diseases and mortality. Many studies have been conducted to elucidate whether weight loss can reverse the adverse health outcomes caused by obesity (e.g. diabetes, CVD etc.). Studies reported by Jensen et al. (2014) have found that weight loss consistently reduces the risk of developing type 2 diabetes in at risk populations (e.g. obese and overweight individuals). The

authors concluded that weight losses of 2.3 to 5.5 Kg at 2 or more years in individuals at risk for type 2 diabetes reduces the risk of developing the disease by 30 to 60 % (Jensen et al., 2014, p3001). Overall, it has been documented that individuals with a BMI within normal range (18.5 – 24.9kg/m^2) had the lowest mortality rate when compared to individuals with higher BMIs and adjusting for smoking (Prospective Studies Collaboration, 2009). There are some reported weight loss risks in the literature such as cholelithiasis or gallbladder disease (Stinton & Shaffer, 2012). Furthermore, it is widely recognized that weight loss results in higher fertility rates and improves reproductive outcome (Clark, Thornley, Tomlinson, Galletley, & Norman, 1998). Nonetheless, the risks are overshadowed by weight loss improved health outcomes and improved quality of life.

1.2.1 Weight Loss and Lifestyle Interventions

The "Look AHEAD (Action for Health in Diabetes)" study provided insights on weight loss health outcomes in patients who were diagnosed with type 2 diabetes. The study lasted eleven years and included 5,145 participants. The study was designed to identify the intentional weight loss effects on cardiovascular morbidity and mortality in individuals with type 2 diabetes (Bray, 2006). The authors reported that individuals with type 2 diabetes who achieved a 2 to 5 % weight loss during 1 to 4 years presented reductions in fasting plasma glucose concentration and glycated hemoglobin (HbA1C). In addition, the "Look AHEAD" study found that individuals with type 2 diabetes who underwent a change in lifestyle to reduce obesity regained about 8% of the weight initially loss after 4 years. However, their HbA1C levels remained below pre-intervention levels despite the partial increase in weight.

It has been documented that many patients that initiate dietary interventions usually regain weight after the intervention has ended. The main cause for weight regain is the non-observance of the diet due to boredom or lose of interest. This has caused many overweight and obese patients to constantly look for a better diet to lose weight. The study by Pagoto and Appelhans (2013) showed that weight loss was strongly associated with adherence to a program rather than to a type of diet. The authors concluded that in order to challenge the obesity epidemic a greater understanding of the factors (environmental, biological, and behavioral) associated with adherence to a lifestyle change need to be addressed (Pagoto, & Appelhans, 2013). Therefore, a comprehensive lifestyle intervention comprised of physical activity, diet and behavioral therapy has a higher possibility to succeed in promoting and maintaining weight loss.

1.2.2 Community-Based Participatory Research Interventions

Community based participatory research (CBPR) is an approach to health research that integrates education and social action to address health disparities problems in a population. CBPR incorporates community theories and fosters communication between the stakeholders to benefit community participants, researchers and health care practitioners alike (Wallerstein & Duran, 2006; Viswanathan et al., 2004). In addition, it is recognized that structural, socio-economic, and racial/ethnic health inequities are well approached by CBPR through collaborative partnerships within the community (Muhammad et al., 2015).

Strategies of CBPR have been used to understand problems in specific areas and identify possible interventions. Goh and collaborators (2009) explored adolescent, parent, and community focus groups regarding the perspectives on barriers to healthy eating and physical activity with the overall aim to identify intervention ideas to address adolescent obesity. The

research recognized the CBPR value in finding potential interventions that are accepted by the community (Goh et al., 2009).

1.3 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity

In 2013, a panel representing experts from the American Heart Association (AHA), American College of Cardiology (ACC) and The Obesity Society (TOS) among other stakeholders developed a set of guidelines and recommendations for primary healthcare providers in order to manage blood cholesterol and reduce cardiovascular risk, as well as overweight and obesity in adults. The objective of stakeholders in the panel was to develop evidence-base statements and recommendations to assist health providers in identifying and managing overweight and obese adults at health risk. The aim of these guidelines was to create practices that fulfill the needs of the majority of the patients. Some of the key findings from high quality evidence review are presented in Table 1.

The 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults were based on high quality randomized trials, meta-analyses and observational studies by a panel of experts on each subject, only when sufficient evidence was available. The overall objective of these guidelines is to assess the risk for CVD and reduce the onset of the disease by encouraging people who are at risk to engage in lifestyle modifications.

Table1. Key Messages Adapted from the 2013 Obesity Guideline and Differences from the 1998 Obesity Guidelines (Kushner & Ryan, 2014).

Key Messages	2013 AHA/ACC/TOS Guidelines for managing Overweight and Obesity in Adults	Difference from 1998 NHLBI Guidelines
Who needs to lose weight?	BMI≥30 or BMI≥25 with ≥ 1 risk factor (including waist circumference, traditional risk factors)	Positions BMI as a screening tool, not a diagnostic tool
What is the role of waist circumference?	Use NIH/NHLBI and WHO/IDF cut points (≥35 in. for women and 40≥ in. for men) to further identify risk	Waist circumference is treated as a risk factor in 2013 guidelines
How much weight loss must be achieved?	Not necessary to achieve ideal BMI Sustained weight loss of 3%-5% produces clinically meaningful health benefits and greater loss produces greater benefits	Greater emphasis on benefits of modest weight loss and importance of maximizing weight loss but does not suggest a BMI target
What is the best diet?	There is no "magic" diet for weight loss Prescribe a calorie-reduced diet based on the patient's health profile and food preferences	Does not endorse any particular dietary approach because all approaches can succeed if accompanied by calorie deficit
How much weight can be lost with lifestyle intervention?	The ideal is 14 or more face-to-face counseling sessions with a trained interventionist in the first 6 months with treatment for 1 year to produce average 8% weight loss	Sets a standard for what a lifestyle intervention should look like, who should deliver it, and what it should aim for
Are there alternatives to in-office counseling?	Telephonic counseling, electronic counseling, and commercial programs have an evidence base for efficacy, albeit with less average weight loss than face-to face counseling	Reflects societal changes in delivery of weight loss intervention
How can weight loss be maintained?	Continue regular contact (monthly or more) with a trained interventionist who helps patients engage in high levels of physical activity (ie, weekly or more), and consume a reduced-calorie diet	Addresses importance of continued therapy to prevent regain
Who should receive bariatric surgery	For adults with BMI≥40 or BMI≥35 with obesity-related comorbidities who have not responded to treatment, advise that bariatric surgery may be an appropriate option and offer referral to an experienced bariatric surgeon	Stronger endorsement for referral for bariatric surgery using the same BMI and health criteria as 1998 guidelines

BMI: body mass index; IDF: International Diabetes Federation; NHLBI: National Heart Lung and Blood Institute; NIH: National Institutes of Health; WHO: World Health Organization.

The recommendations are categorized based on the level of evidence available, consequently a "Grade A" recommendation would mean that based on scientific evidence there is a high confidence of a substantial benefit. Whereas a "Grade C" recommendation would mean that there is a low evidence that the recommendation provides a small benefit toward the overall goals (Table 2). Nevertheless, "Grade B or C" does not mean that the recommendation is weak simply that studies are unavailable.

Table 2. Strength of Recommendation Adapted from the 2013 AHA/ACC/TOS Obesity Guideline. (Jensen et al., 2014).

Grade	Strength of Recommendation
A	**Strong recommendation** There is high certainty based on evidence that the net benefit* is substantial.
B	**Moderate recommendation** There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate
C	**Weak recommendation** There is at least moderate certainty based on evidence that there is a small net benefit
D	**Recommendation against** There is at least moderate certainty based on evidence that it has no net benefit or that risks/harms outweigh benefits
E	**Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Panel recommends.")** Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Panel thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area
N	**No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.")** Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Panel thought no recommendation should be made. Further research is recommended in this area.

*Net benefit is defined as benefits minus risks/harms of the service/intervention.

The guidelines were endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacist Association, American Society for Nutrition, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipids Association, Preventive Cardiovascular Nurses Association,

and The Endocrine Society and WomanHeart: The National Coalition of Woman with Heart Disease.

1.3.1 Recommendation for Body Mass Index

With a "grade A" level of confidence the 2013 AHA/ACC/TOS Guideline recommend to use a BMI range from 25 to 29.9 kg/m^2 to classify overweight and a BMI cut-off point of 30 kg/m^2 and higher to classify obesity in adult individuals who could be at high risk of CVD (Table 3). It is also recommended to use BMI≥30 as an indicator to identify adult individuals with potential high risk of mortality.

The guidelines recognize the shortcomings of using BMI as a rubric to measure overweight and obesity. BMI presents limitations in predicting the body fat association with health risk on an individual basis. For instance, abdominal fat is associated with superior health risk than fat located in other regions of the body; however, BMI measurements cannot differentiate the distribution of body weight. Another limitation of BMI is that when life style interventions are applied, this measurement is not an accurate indicator of an improved health outcome, sometimes causing disappointment and diet and exercise regimens abandonment. Ross and Janiszewski (2008) reported that physical activity was strongly associated with reductions in coronary heart disease independent of weight or BMI. The authors concluded that an apparent lack of weight loss should never be a reason to stop healthy behaviors (Ross & Janiszewski, 2008).

1.3.2 Recommendation for Waist Circumference

To account for BMI measurement limitations, the guidelines suggest to measure waist circumference (WC) with a "grade E" level of confidence in adult individuals with BMI classifications at overweight and obese levels. Many authors recommend measurement of the WC when predicting obesity health outcomes, since it accounts for the abdominal fat that is strongly associated with metabolic syndrome (Booth, Hunter, Gore, Bauman, & Owen, 2000; Rexrode et al., 1998; Zhu et al., 2002; Després & Lemieux 2006). Moreover, according to the World Health Organization (WHO) obesity report (1998), if the documentation of the WC were standardized as a measurement of abdominal fat accumulation over time, the health burden of obesity would be easier to predict. Abdominal fat is associated with health risks such as organ fat infiltration, pro-thrombotic and pro-inflammatory conditions (Van Gaal, Mertens, & Christophe, 2006; Jensen et al., 2014). However, there is debate among health organizations about the WC cut-off points that relate to an elevated risk.

The National Institutes of Health (NIH) provide guidelines to classify obesity (Table 3) in which BMI and WC are used (Booth, Hunter, Gore, Bauman, & Owen, 2000). These guidelines recommend that patients with a BMI of 25 to 34.9 kg/m^2 and WC greater than 102 cm (40 in) for men and 88 cm (35 in) for woman are associated with a higher risk for type 2 diabetes, hypertension, and coronary heart disease.

Table 3. "Classification of overweight and obesity by BMI, waist circumference, and associated disease risk" Adapted from the World Health Organization (Aronne, 2002).

			Disease risk *	
	BMI (kg/m^2)	Obesity Class	Men ≤ 40 in (102 cm) Women ≤ 35 in (88 cm)	>40 in (102 cm) >35 in (88 cm)
Underweight	<18.5			
Normal**	18.5 to 24.9			
Overweight	25.0 to 29.9		Increased	High
Obesity	30.0 to 34.9	I	High	Very High
	30.0 to 34.9	II	Very High	Very High
Extreme obesity	≥40	IIII	Extremely High	Extremely High

*Disease risk for type 2 diabetes, hypertension, and coronary heart disease.
**Increased weight circumference can also be a marker for increased risk even in persons of normal weight.

Although there is a lack of consensus between health agencies (e.g. WHO, NIH, International Diabetes Federation) regarding the WC risk cutoff points, studies have presented unequivocal evidence that supports a linear correlation between WC and health risks (de Koning, Merchant, Pogue, & Anand, 2007; Vazquez, Duval, Jacobs, & Silventoinen, 2007; Emerging Risk Factors Collaboration, 2011). Therefore, it has been suggested that BMI data in conjunction with WC can provide a better health risk assessment of the patient than BMI alone (Rexrode et al., 1998 & Janssen, Katzmarzyk, & Ross, 2002).

1.3.3 Guidelines for Overall Dietary Composition

One of the primary objectives regarding the treatment and prevention of obesity is to identify patients at risk and implement weight loss interventions. Health providers play a key role in these interventions given that they will promote dietary strategies that must be effective and adequate for each patient. The common denominator between all dietary plans to tackle

obesity is the need to alter the energy balance in the patient by creating an energy deficit. Accordingly, there must be a reduction in energy intake from food since it is very difficult for most overweight and obese patients to create an energy deficit by physical activity alone. Based on strong evidence (Grade A), the 2013 AHA/ACC/TOS Guideline recommends any of the following methods to reduce caloric intake. Prescribe a diet with specific energy intakes of 1200-1500 kcal/day for woman and 1500-1800 kcal/day for man, where the adjusted target of energy intake should be less than the required for energy balance. It recommends the use of evidence based diet approaches that restricts certain food types to create an energy deficit. Prescription of a diet with an energy deficit of 500 to 750 kcal or 30% energy deficit after the patient daily energy requirement and physical activity levels are calculated (Jensen et al., 2014). Most importantly, the guidelines suggest diets for weight loss as part of a comprehensive lifestyle intervention.

Interestingly, a metadata study reported that obese and overweight adults under dietary intervention achieve an average maximum weight loss at 6 months with smaller losses maintained for up to two years (Jensen et al., 2014). The studies did not investigate the causes for weight regain after an initial intervention, nevertheless the authors suggest that loss of interest and commitment as well as metabolic adaptation could be the causes.

Over time, adjustments to the diet must be made to achieve a continued weight loss because the energy requirements will decrease as patients lose weight. Jensen et al. (2014) studied the metadata from twelve trials with different dietary interventions and concluded that all different dietary approaches can promote weight loss when reduction in energy intake is achieved. In addition, the authors reported that when compared to an energy deficit diet, none of the dietary approaches mentioned in the guidelines offered a superior performance. The study

also concluded that further large scale research on optimal dietary patterns that include high and no risk populations is needed in order to provide overweight management guidelines.

1.3.4 Guidelines for Weight Loss Intervention

By comparing lifestyle interventions with usual diet groups, ten randomized controlled trials were analyzed by the 2013 AHA/ACC/TOS Guideline to validate that physical activity, diet and behavioral therapy are essential components in comprehensive lifestyle interventions in order to succeed with weigh loss promotion or maintenance (Jensen et al., 2014). The 2013 Guideline recommend for overweight and obese patients to engage in comprehensive lifestyle interventions that include behavioral strategies that increase the individual's adherence to a low calorie diet and increase physical activity.. Based on strong evidence (Grade A), the 2013 guideline recommends that three components are included in effective comprehensive-lifestyle intervention; 1) calorie intake reduction, 2) increase physical activity and 3) the use of behavioral modification strategies. In addition, it is recommended that weight loss interventions should be provided on-site and with a large number of sessions (i.e. 14 or more sessions are suggested) by a trained interventionist. For overweight and obese individuals who have lost weight, the guidelines recommend long-term (i.e. one year or more) weight loss maintenance programs (Jensen et al., 2014).

Apart from diet, comprehensive interventions prescribe aerobic activity to increase the energy expenditure; some studies recommend more than 150 minutes of brisk walking per week (Jensen et al., 2014). Behavior therapy is a key aspect in any comprehensive lifestyle intervention since it provides the patient with a set of skills that help them maintain the modified eating and physical activity behaviors. Self-monitoring of food intake, physical activity and body

weight is often recommended in behavior therapy (Jensen et al., 2014). Often, studies add different components to the behavior therapy such as slow rate eating, problem solving and relapse prevention.

Strong evidence (Grade A) suggests that better results are achieved when the duration of the program is beyond 6 months. The studies (Jensen et al., 2014) concluded that lifestyle interventions with frequent on-site group or individual treatment produced an average weight loss of 8 kg in 6 months (approx. 5%-10% body weight reduction), which are greater than those produced by usual care. The guidelines report with a high degree of certainty (Grade A) that even minor, weight losses of 3-5% are expected to result in clinically meaningful health benefits (i.e. reduction of triglycerides, blood glucose, HbA1C and the risk to develop type 2 diabetes). The 2013 AHA/ACC/TOS Guideline also reports the relationship between weight loss and hypertension risk. The guidelines report that with at a weight loss of 5% or more, a mean reduction of 3 and 2 mm Hg is observed in systolic and diastolic blood pressure respectively.

In summary, the 2013 AHA/ACC/TOS Guideline indicates that comprehensive lifestyle interventions with frequent patient contacts had the highest average weight loss at 6 to 12 months, after which a weight increase of 1 to 2 kg per year is associated (Jensen et al., 2014). Nevertheless, long-term weight loss (i.e. over 12 months) in lifestyle interventions remains more successful than regular care (Pi-Sunyer et al., 2007; Jensen et al., 2014).

1.4 Healthy People 2020 Goals Related to Overweight and Obesity

Healthy People is a national wide heath agenda originally created in 1979 and generated by the U.S. Department of Health and Human Services though the Office of Disease Prevention and Health Promotion. The ultimate goal of Healthy People 2020 (HP 2020) is to attain a society with high-quality and longer lives (free of preventable diseases, disability, injury, premature death), and reach health equity, as well as improve health among all groups of people living in the U.S. To attain its goals, Healthy People initiative recommends to promote partnerships between communities and other sectors in order to encourage individuals to make informed health decisions and quantify the efficacy of prevention activities. Healthy People 2020 is the product of the continuance tradition, after more than 30 years of input from the 4 preceding Healthy People initiatives, and grounded on previous progresses towards established targets.

Healthy People 2020 includes 42 topics areas with nearly 600 objectives with a recent inclusion of a new section named "HP2020 & Leading Health Indicators". The Leading Health Indicators (LHIs) section focus on high-priority health issues and are organized under 12 topic areas to assess key points in the health of the nation. The selected health indicators were designed to address determinants of health, healthy behavior and healthy development across all age-stages in order to improve health disparities and the overall population health.

There are a series of goals in HP 2020 containing several topics and objectives targeting the obesity problem and some of them are in alignment with this project. Under the new HP2020 the specific Health Indicator, targeted as a high priority health issue, is related to obesity among adults who are 20 years and older and it is under the Leading Health Topic "Nutrition, Physical Activity, and Obesity." The reasoning for obesity been a high priority issue is the provide

guidance to overcome high rates of obesity in the U.S.. The Nutrition and Weight Status topic (NWS) is in alignment with this project. Objective 7 focuses on increasing the proportion of worksites that offer nutrition or weight management classes or counseling. The NWS objective 8 is to increase the proportion of adults who are at a healthy weight with a 10% target of improvement. The NWS objective 9 (LHI) is to reduce the proportion of adults who are obese with a target of 30.5 percent in general and recognizes a gender disparity. The NWS objective 17 is to reduce consumption of calories from solid fats and added sugars in the population aged 3 years and older.

Additional topics in HP2020 that are indirectly aligned and addressed with weight loss interventions include Heart Disease and Stroke, HDS objective 1 is to increase overall cardiovascular health in the U.S. population. HDS objective 5 is to reduce the proportion of adults with hypertension. HDS objective 9 and 10 (under development) are to increase the proportion of adults with prehypertension and hypertension who met the recommended guidelines for BMI and physical activity. HDS objectives 13 and 14 are to increase the proportion of adults with elevated LDL cholesterol who have been advised by a health care provider regarding cholesterol-lowering management, including lifestyle changes such as physical activity and weight control. Under the Arthritis topic objective AOCBC-7.1 is to increase the proportion of overweight and obese adults with doctor-diagnosed arthritis who receive health care provider counseling for weight reduction. And under the Diabetes topic the objective D-16 is to increase the prevention behaviors in persons at high risk for diabetes with prediabetes increasing levels of physical activities, lose weight and reduce the amount of fat or calories in their diets (Healthy people 2020).

CHAPTER 2: OBJECTIVE, PURPOSE & JUSTIFIATION OF THE STUDY

2.1 Objective of the Study

The objective of this study was to conduct a secondary data analysis to compare the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in adults to the clinical outcomes obtained in the PLMM intervention implemented among Hispanic adults from 2009 to 2013 in El Paso, Texas. A secondary data analysis was conducted to select the appropriate sample of participants at baseline and compare their clinical outcomes after the 4-month CHW/PS led intervention. The clinical outcomes of weight and BMI loss, WC reduction and changes in blood pressure reached after the CHW/PS intervention were compared to the evidence-based recommendations from the 2013 AHA/ACC/TOS Guideline.

2.2 Purpose of the Study

The purpose of the study was to investigate whether the CHW/PS facilitated weight loss among Hispanic participants in the PLMM intervention that is consistent with the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. The study aim was to identify participants who achieved weight loss after the completion of the 4-month PLMM intervention and compare the individual's clinical outcomes among overweight and obese participants. In addition, the study explored whether BP changes occurred among those participants who completed the PLMM intervention. The cases under the secondary data analysis were those that were identified as needing to lose weight at baseline in the PLMM intervention based on the 2013 Guideline recommendations. Once overweight and obese participants were identified, their clinical outcomes after the PLMM intervention were evaluated. The 2013 AHA/ACC/TOS Guideline was used to identify and select participants who were at elevated risk

for CVD based on the BMI and WC criteria among the participants who enrolled in the PLMM intervention. According to the 2013 Guideline and based on strong evidence, even a modest sustained weight loss of 3% to 5% will result in clinically meaningful health benefits for a patient with CVD risk factors. The clinical health benefits that have an effect on CVD risk factors with a modest sustained weight loss include reduction in triglycerides, blood glucose, HbA1C, and reduction of the risk to develop type 2 diabetes. According to the evidence, the greater the weight loss the greater the benefit; larger weight losses will produce blood pressure (BP) reduction, LDL and HDL improvement as well as reduction in triglycerides and blood glucose.

3.3 Justification of the Study

Based on the gaps of evidence that are stated in the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults, research is needed to better understand and improve the efficiency of on-site lifestyle interventions on key populations including racial/ethnic groups. Therefore, it is anticipated that this study of the 4-month PLMM intervention that used guideline recommendations as a reference, will provide insights related to a lifestyle interventions led by CHW/PS among Hispanics living in the U.S.-Mexico border.

CHAPTER 3: RESEARCH QUESTIONS, AIMS, AND HYPOTHESIS

3.1 Data Analysis at Baseline:

Following the recommendations in the 2013 AHA/ACC/TOS Guideline for the management of overweight and obesity the objective was to determine how many participants who were enrolled in the PLMM intervention met the eligibility criterions.

3.1.1 Research Question 1

What is the proportion of female and male participants in the PLMM intervention that met the BMI criterion established by the 2013 AHA/ACC/TOS Guideline at baseline?

Specific Aim 1

To identify the proportion of overweight or obese Hispanic adults who were enrolled in the PLMM intervention using BMI. The selection was done by using the cut-off points of BMI recommended in the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. The BMI cut-off points established by the 2013 guideline for male and female individuals at higher risk are: BMI $\geq$ 25-29.9 kg/m^2 for overweight, and $\geq$30 kg/m^2 for obese.

3.2.1 Research Question 2

What is the proportion of female and male participants in the PLMM intervention that met the waist circumference criteria as established by the 2013 AHA/ACC/TOS Guideline at baseline?

Specific Aim 2

To determine the proportion of Hispanic adults by sex and BMI categories with increased waist circumference enrolled in the PLMM intervention and categorize them using the current cut-off points established by the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. The Panel of the 2013 Guideline recommended by expert opinion that an increased risk cut-off points for waist circumference are ≥88 cm or ≥35 in for women and ≥102 cm or ≥40 in for men.

3.2 Data Analysis at Post-Intervention:

After identifying participants at baseline in the PLMM intervention who needed to lose weight, identify the number of participants who achieved a clinically meaningful health outcome consistent with the recommendations of the 2013 AHA/ACC/TOS Guideline.

3.2.1 Research Question 3

What is the proportion of female and male participants from the PLMM intervention that achieved the recommended weight loss of 3%-5% established by the 2013 AHA/ACC/TOS Guideline at post-intervention?

Specific Aim 3

Among selected participants who completed the 4-month PLMM intervention, determine the proportion of participants by sex and BMI categories who achieved a reduction in body weight of 3%-5% established by the 2013 AHA/ACC/TOS Guideline as an outcome that will

produce clinically health benefits. In addition, determine the percentage of participants who achieved 10% of body weight.

3.2.2 Research Question 4

What is the proportion of female and male participants that achieved a clinically meaningful health outcome such SBP or DBP reduction after completion of the 4-month PLMM intervention?

Specific Aim 4

Among the selected participants who completed the 4-month PLMM intervention, identify BP changes by sex and BMI categories endorsed by the 2013 AHA/ACC/TOS Guideline as a dose-response relationship with weight loss achieved by lifestyle intervention. In addition, identify the proportion of participants that reached the clinically meaningful health reduction of 3 mmHg for SBP or 2 mmHg for DBP.

3.3 Alternative & Null Hypotheses

Alternative Hypotheses

It is hypothesized that among selected Hispanic adults eligible to lose weight, as established by the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults, a meaningful health goal of 3% of weight loss after the completion of the 4-month PLMM intervention was achieved. A secondary hypothesis is that among the selected sample of Hispanic adults who completed the PLMM intervention and reached or exceed the weight loss reduction of 5% will have a clinically meaningful outcome in blood pressure measurements.

Null Hypothesis

It is hypothesized that among the selected Hispanic adults eligible to lose weight, as established by the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults, failed to achieve the meaningful health goal of 3% of weight loss after the completion of the 4-month PLMM intervention. A secondary hypothesis is that among the selected sample of Hispanic adults who completed the PLMM intervention and reached or exceed the weight loss reduction of 5% failed to achieve a clinically meaningful outcome in blood pressure.

CHAPTER 4: METHODS & MATERIALS

4.1 Overview of the Study

This is a secondary data analysis of the cross-sectional data collected from the PLMM intervention. A comparison of the recommendations of the 2013 AHA/ACC/TOS Overweight and Obesity Management in Adults Guideline was made to the clinical outcomes of PLMM intervention. This study uses the PLMM data to identify overweight and obese Hispanic adults with a large WC at baseline. This study also uses the data obtained after the 4-months intervention was completed. Univariate and bivariate analysis were calculated in order to identify overweight and obese participants as those who met the WC criterion. Variables used in the study included BMI, gender and age groups: 29 years or less, 30-39 years, 40-49 years, 50-59 years and 60 years and more.

According to 2013 AHA/ACC/TOS Guideline and based on strong evidence, overweight adults may be at elevated risk for CVD and obese adults may be at elevated risk of mortality from all causes. After converting the variables of interest (height & weight gathered upon enrollment) from imperial units to the international unit system, individual BMI were calculated using the formula: [Weight (kg)/Height^2 **(**m^2)]. The BMI cut-off points used in this analysis were as follow: overweight (25 ≤ 30 kg/m^2); obese class I (30≤35 kg/m^2); obese class II (35≤40 kg/m^2); and obese class III (≥40 kg/m^2) (Jensen et al., 2014).

Based on the 2013 guideline, all overweight and obese individuals with one or more risk factors for increased CVD (diabetes, prediabetes, hypertension, dyslipidemia, and elevated waist circumference) or other related comorbidities are at high health risk. Elevated WC, if present in overweight individuals was considered as a risk factor in this study. The original variable for WC

was converted from inches to centimeters. According to 2013 AHA/ACC/TOS Guideline and based on expert opinion the cut-off points used for WC were ≥ 88cm (≥35in) for women and ≥ 102 cm (≥40in) for men (Jensen et al., 2014). All participants categorized as obese were included in the secondary data analysis whether or not they met the WC criterion.

The post-intervention data was used to analyze the meaningful health outcomes reached by all overweight with large WC and obese participants that completed the 4-month intervention according to the 2013 guideline. To summarize, this secondary data analysis comprises an assessment of selected participants who completed the PLMM intervention. An evaluation of their body weight reduction and concomitant changes in their blood pressure (BP) was performed. Univariate and bivariate analysis were calculated in order to identify the percentages of weight loss and BP changes in systolic blood pressure (SBP) and/or diastolic blood pressure (DBP). The results were classified and explored using the variables: BMI classification upon enrollment, gender and age groups.

According to 2013 AHA/ACC/TOS Guideline and based on strong evidence, selected participants that reduce 3% or more of their body weight will have a beneficial effect on their CVD risk factors, and in general morbidity and mortality. The achievement in body weight reduction was calculated and evaluated; as well as the identification of the number of participants who reached the goal of 3%, 4% or 5% of weight loss. In addition, larger weight losses such as 10% that could produce greater benefits were also explored (Jensen et al., 2014).

According to 2013 AHA/ACC/TOS Guideline and based on strong evidence a weight loss of 5% or greater is likely to result in BP reduction (Jensen et al., 2014). Therefore, among the selected participants that completed the 4-month PLMM intervention, changes in BP,

specifically mean SBP, and mean DBP were analyzed. In addition, the number of participants that reached the clinically significant reduction of 3 mmHg for SBP and 2 mmHg DBP were explored.

4.1.1 Promotora-Led Mi Corazón Mi Comunidad Intervention

The PLMM Intervention was part of the Health Education and Assessment Research Team (HEART) project, a community-based participatory research (CBPR) funded by the National Institutes of Health/National Institute on Minority Health and Health Disparities (Balcázar et al., 2012). The goal of the PLMM intervention was to reduce risk factors for CVD in residents living in two low-income areas (zip codes 79907 and 79915) in El Paso, Texas. These two zip codes were chosen due to its high number of Mexican-American residents with lower access to health care as compared to the city's average. Community Health Workers (CHW) or Promotores de Salud (PS) trained by the designers of the PLMM study facilitated the intervention.

The 16-week PLMM intervention enrolled 753 participants in five cohorts and 411 completed the program. The PLMM intervention incorporated practice methods identified by the CDC Task force on Community Preventive Services. Stakeholders including three academic institutions, a health care center, city parks and recreation supported the intervention. The PLMM intervention's objective was to promote participants' healthy behaviors by providing resources such as heart-health education, physical activity, and nutrition education (Balcázar et al., 2012). The CHW/PS provided the heart-health education through the "Mi Corazon Mi Vida" Promotor curriculum developed by NHLBI for Mexican-American populations to encourage healthy behaviors.

The 4-month intervention organized physical activities that were provided for the duration of the study. These included walking sessions in the park and in-door classes such as swimming and aerobics. In addition, PS provided participants with nutrition education, cooking demonstrations, and grocery store tours (de Heer et al., 2015).

4.2 Theoretical Framework

The Transtheoretical Model (TTM) (Prochaska, Redding & Ever, 2002) provides the framework to modify or change harmful behaviors. As stated in this behavioral model, change occurs in stages over time and individuals go through many decision processes "little decisions" that finally will take part of the desired behavioral change. The TTM and its six stages has been useful as theoretical framework in weigh management as outlined by other researches (Johnson et al., 2008 & Rossi et al., 1994 & Seals, 2007). The Stages of Change are constructed for six progression levels (pre-contemplation, contemplation, preparation, action, maintenance, and termination) where the individual move at their own pace towards the behavioral change (Figure 2). To move from one stage to another in the TTM the individual will have to engage in several processes, key constructs in this theory are self-efficacy and decisional balance. Self-efficacy is the person's belief that he or she can change a specific behavior and this should increase as the individual progress through the stages. Decisional balance is the process of weighing the pros and cons that will determine decision-making to move or not toward change. The individuals may enter in this loop of progression at any stage, meaning that they might not start at all the first level of the TTM.

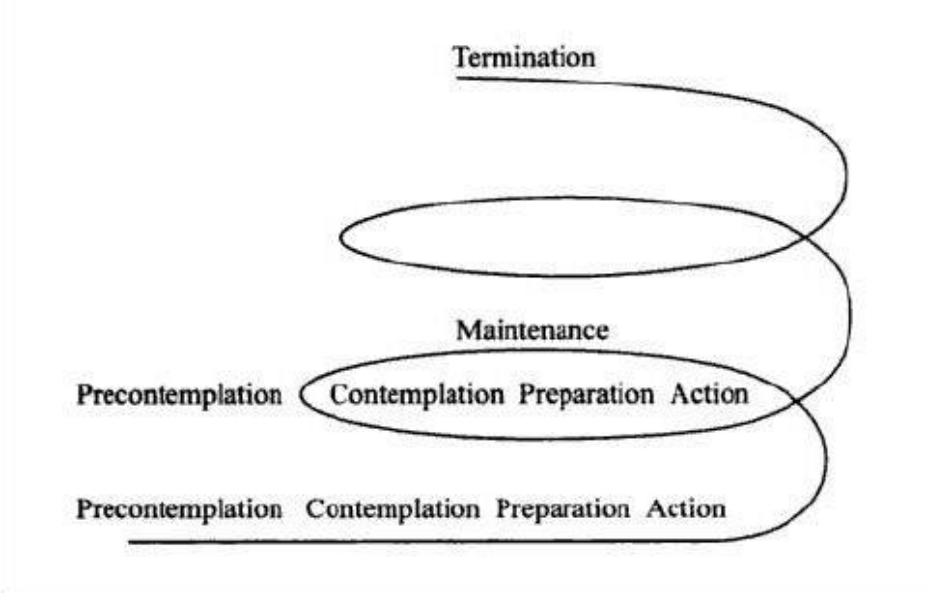

Figure 2. Spiral model of the stages of change in the Transtheoretical Model (Prochaska & DiClemente, 1992).

Treatment of overweight and obesity requires a multidisciplinary approach that includes diet changes, physical activity plan and behavioral therapy, as well as readiness assessment to make lifestyle changes to achieve weight loss. Once the individual's readiness to make a lifestyle change is determined, appropriate intervention and counseling can be directed to the individual to make the commitment more efficient. The majority of overweight and obese patients usually are in the preparation, action or maintenance stages and awareness of their health risk positions these patients into the advance stages of readiness to lose weight, improve diet and/or to increase physical activity (Wee, Davis & Phillips, 2005).

The 2013 AHA/ACC/TOS Guideline developed for the management of overweight and obesity in adults are supported for the TTM and by expert opinion the panel advises to assess the readiness of the patient to make lifestyle changes in order to achieve weight loss (Jensen et al., 2014). Regardless of the participant's weight or stage of readiness for change, either prevention

or loss weight counseling should occur among high-risk populations. According to Wee, Davis & Phillips findings (2005), the awareness of the health risk due to overweight and obese should be advice from physician to patients and provide counseling about weight loss and lifestyle changes. The idea of overweight or obesity prevention, detection and treatment cannot rely only on primary care providers at one patient at a time. CHW or PS could play an important role as the first front in the battle against obesity, through community education, early detection, appropriate counseling and prompt resources connection and treatment.

4.3 Population

The study was conducted in the city of El Paso located at the far west of Texas directly on the border region of the U.S. and Mexico. The U.S. metropolitan area covers all El Paso and Hudspeth counties with an estimated population of 833, 487 in 2014 (U.S. Census Bureau, 2014). El Paso, Texas is mostly a Mexican-American community with approximately 81.2% of its population being from Hispanic or Latino origin (versus the national average 17.4%). According to the U.S. Census Bureau (2014), the age distribution of the population was equivalent to state and national averages: female population 51% (U.S. avg. 50.8%), persons under 18 years 28.3 % (U.S. avg. 23.1%), and persons under 5 years 8.1% (U.S. avg. 6.2%). However, the estimated population living below the poverty level was 23.3% in El Paso; higher than average in Texas (17.6%) and in U.S. (15.4%). Also the residents who spoke at home other language than English were 73% (U.S. avg. 20.7%) and foreign-born occupants were 26% (U.S. avg. 12.9%). Furthermore, the median household income reported in El Paso was around $40,157; whereas in Texas and U.S. was higher ($ 51,900 and $53,046 respectively) and the residents without insurance was 28.4% above the national average (10.4% in 2014) higher. The educational attainments were lower than the state and national averages; people aged 25 years or

more 74% (vs. 81.2% and 86.0%) had at least a high school degree and 20.7% (vs. 26.7% and 28.8%) a bachelor's degree or higher (U.S. Census Bureau, 2014).

4.4 Sample Size

The PLMM intervention aimed at the reduction of CVD risks factors among residents of El Paso, Texas. The eligibility criteria for this secondary data analysis was 18 years or older and availability of clinical measurements (Height & Weight &Waist Circumference) obtained at baseline. The exclusion criteria was lack of identification as Hispanic (either by self-identification as Hispanic, Spanish as language of preference and/or place of birth in Mexico). For the purpose of this secondary data analysis, a convenience sample of 705 participants resulted from total initial enrollment of 753 in the PLMM intervention.

4.5 Recruitment and Selection

Promotores de Salud or CHW recruited participants at various community health fairs and recreation centers and by means of personal contacts and referrals, in addition to radio and television Spanish broadcasts (Balcázar et al., 2012).

The inclusion criteria for the PLMM participants were adults, capable to participate in physical activities, and residents in the 2 selected zip codes (79907 & 79915) with the intention of remain at the same residence for the next 10 months (Balcazar et al., 2010). The exclusion criteria were being or planning on becoming pregnant within the next 6 months, intentions to move out from the zip codes area in the next 6 months, were current members of the YWCA, restriction of participating in any type of physical activity by a doctor, medical history of severe heart condition and if participants suffered any injure in the previous 6 month of the study.

4.6 IRB Approval & Ethics

This secondary data analysis uses information from the PLMM database. Access to personal identification information from participants has been protected and coded. Therefore, the current study is exempt from IRB evaluation according to the U.S. Department of Health & Human Services regulation 45 CFR 46. 101 (b)(4). The electronic databases are kept on original flash-drives locked in a file cabinet inside the P.I.'s office and their use is only on password-protected computers.

The Institutional Review Board granted approval for the secondary data analysis of the PLMM intervention (IRB number: 86134-20).

4.7 Data Collection Instruments

Participants completed a questionnaire at enrollment and after 16-week when the intervention was completed. The questionnaires were completed in either English or Spanish. Information gathering included demographic information, educational and socio-economic status, acculturation, food frequency consumption, and intentions to engage in healthy eating (Balcázar et al., 2012). Trained research staff following standard procedures collected clinical data at baseline and 4 months; the clinical measurements assessed included height, weight, waist and hip circumference, and systolic/diastolic blood pressure. For the purposes of this secondary data analysis, the following variables were used: demographic and clinical measurements.

4.7.1 Demographics

Demographic information obtained from the selected sample of participants for the purpose of this study included: sex, age, marital status, time living in the U.S.A., annual

household income, health insurance, ethnicity, place of birth, language of preference, years of education, and employment.

4.7.2 Clinical Measurements

The participants' measurements obtained at baseline and at 4-month were available from the original database and converted from imperial units to the international unit system. The variables of interest for this secondary data analysis were the following: height, waist circumference (WC), weight, mean SBP and mean DBP. BMI was calculated using the formula (weight [kg] / height^2 [m^2]).

4.8 Statistical Analysis Plan

Data was selected to create a new SPSS database for the purpose of this study. The database included Hispanic adult participants only; excluding those with a different ethnicity. The IBM SPSS statistic software (SPSS-version 22) was used for statistical analysis. Both graphical displays and numerical measures were used to explore and summarize the data: frequencies and/or percentages were computed for categorical variables and central tendency and variability measures were obtained for each continuous variable.

Gender and BMI category comparison were made via either paired t tests or chi-square tests. Linear regression models were performed to evaluate the correlation between the participant's demographics (e.g. education, income, age, gender etc.) and weight loss reduction, as well as changes in SBP and DBP.

CHAPTER 5: RESULTS

5.1 Descriptive Statistics of the Selected Participants

The PLMM intervention implemented at the U.S. – Mexico border promoted healthy behaviors among participants by providing heart-healthy education including nutrition education classes and physical activities. Initially, the PLMM intervention enrolled 753 participants from 2009 to 2013. From the original sample, 48 participants were excluded for the following reasons: 2 participants did not meet the age requirement, 45 participants were not identified as Hispanics and the WC measurement of 1 participant was not available. After conducting a screening for the inclusion and exclusion criteria for this secondary data analysis, 705 Hispanic participants were included in the analysis with the purpose of assessing the effectiveness of the PLMM intervention in comparison to the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obese in Adults. At baseline, 500 participants were eligible to lose weight according to criterions in the 2013 AHA/ACC/TOS Guideline, 285 participants from the selected sample completed the 4-month intervention and were assessed for the effectiveness of the PLMM intervention.

The demographic characteristics of the PLMM selected sample of participants for the purpose of this secondary data analysis are shown in Table 4. The average age of the eligible Hispanic participants at baseline was 46.3 (SD± 12.60) years with more than three-fourths of the sample being females (86.2%). After the PLMM intervention, only 57% of the participants were retained and their mean age was 48.2 (SD±12.2) years while the proportion by gender was 89.8% females and 10.2% males. At baseline, the majority of participants selected Spanish as their language of preference (84.4%) and nearly two-thirds were born in Mexico (64.3%). The

majority of eligible Hispanic adults reported an average of 11.85 (SD± 3.7) years of education completed at baseline and only one-third of participants achieved or continued their education after high school; furthermore, 62.1% of the participants selected Mexico as the main place where they obtained their education.

Upon enrollment in the PLMM intervention, more than three-fourths (76.46%) of participants reported living in the U.S. for more than 10 years; the average living time in the U.S. of the eligible participants was 28.77 years (SD± 17.39), two more years than the original sample. Among the PLMM participants selected for the purpose of this study, 71.4% reported having an annual income below US $20,000. About 60% of the selected sample of participants reported being unemployed at enrollment and the main selected reason (48.24%) was "taking care of house or family." Among two-fifths of participants that reported being employed, 59.21% were employees of private companies or working for wages. The results also show that almost half of participants (47.6%) did not have any form of medical insurance. The marital status of 55.7% of participants was married or living with a partner. Half of the selected sample of Hispanic adults reported being house owners or being in the process of buying a house.

Table 4. Demographic Characteristics of the Selected Sample of Hispanic Adult Participants from the PLMM Intervention upon Enrollment.

Variable	PLMMI (N=705) Mean±SD or n (%)	Baseline (n=500) Mean±SD or n (%)	Post-Intervention (n=285) Mean±SD or n (%)
Age, years	44.7±13.19	46.3±12.60	48.2±12.21
Gender			
Male	111 (15.7)	69 (13.8)	29 (10.2)
Female	594 (84.3)	431 (86.2)	256 (89.8)
Language of Preference			
Spanish	607 (86.1)	422 (84.4)	245 (86.0)
English	98 (13.9)	78 (15.6)	40 (14.0)
Place of Birth			
Mexico	459 (65.1)	321 (64.3)	187 (65.8)
United States	242 (34.3)	176 (35.3)	95 (33.5)
Other (Puerto Rico)	3 (0.4)	2 (0.4)	2 (0.7)
Years of Education	11.93±3.67	11.85±3.72	11.79±3.56
Place of Education			
Mexico	429 (60.9)	308 (62.1)	181 (64.0)
United States	263 (37.3)	186 (37.5)	100 (35.3)
Other	4 (0.6)	2 (0.4)	2 (0.7)
Time Living in the US	26.77±17.67	28.77±17.39	29.88±17.86
Less than 10 years	162 (23.0)	93 (19.2)	53 (19.1)
10-20 years	134 (19.0)	82 (16.9)	41 (14.8)
20-30 years	129 (18.3)	102 (21.0)	54 (19.5)
More than 30 years	263 (37.3)	208 (42.9)	129 (46.6)
Marital Status			
Never married	118 (16.7)	75 (15.0)	31 (10.9)
Married or in Couple as marriage	393 (55.7)	278 (55.7)	172 (60.6)
Divorced, Separated or Widowed	191 (27.1)	146 (29.3)	81 (28.5)
Household Income			
Less than 10k	250 (35.5)	177 (35.7)	92 (32.4)
10k to 20k	249 (35.3)	177 (35.7)	104 (36.6)
More than 20k	200 (28.4)	142 (28.6)	88 (31.0)
Employed			
No	430 (61.0)	307 (61.5)	183 (64.4)
Yes, full time	163 (23.1)	114 (22.8)	55 (19.4)
Yes, part time	109 (15.5)	78 (15.6)	46 (16.2)
Health Insurance			
No Insurance	342 (48.5)	236 (47.6)	121 (42.9)
Private Insurance	142 (20.1)	100 (20.2)	60 (21.3)
Medicare or Medicaid	97 (13.8)	72 (14.5)	48 (17.0)
Other	120 (17.0)	88 (17.7)	53 (18.8)

5.2 Specific Aim 1: Identification of Overweight and Obese Participants at Baseline

Specific aim 1 was to identify and select a sample of Hispanic adults enrolled in the PLMM intervention who had a BMI within the following categories: overweight (25 ≤ 30 kg/m$^{2)}$, obese class I (30≤35 kg/m^2), obese class II (35≤40 kg/m^2) and obese class III (≥40 kg/m^2).

A Univariate Analysis was conducted in order to identify the proportions of overweight and obese participants as a criterion of eligibility. Among the 705 Hispanic adult participants who met the inclusion criteria from the PLMM intervention, a total of 85.1% of participants (600) had a BMI corresponding to overweight or obese (class I, II and III) and consistent with the 2013 AHA/ACC/TOS Guideline (Table 5).

Table 5. Percentages of BMI categories from selected Hispanic Adults at baseline.

BMI by Category	**PLMM Participants (N=705) N (%)**	**2013 Guideline Cut points**	**Selected Participants % (n) (n=600)**
Underweight	3 (0.4)	≤18.5	-
Normal Weight	102 (14.5)	18.5 ≤ 24.9kg/m^2	-
Overweight	218 (30.9)	25 ≤ 30 kg/m^2	218 (36.3)
Obesity class I	209 (29.6)	30≤35 kg/m^2	209 (34.8)
Obesity class II	99 (14.0)	35≤40 kg/m^2	99 (16.5)
Obesity class III	74 (10.5)	≥40 kg/m^2	74 (12.3)

A total of 3 participants were underweight and 102 were normal weight; therefore, 14.9% of the PLMM participants were excluded from further analysis.

Among the 600 participants selected at baseline, 83.7% (502) were female and 16.3% (98) were males. The majority of participants belong to the overweight category with 36.3% (218) participants, followed by 34.8% (209) participants in obesity class I. 16.5% (99) were from obesity class II and 12.3% (74) were in obesity class III. At baseline, almost two thirds of participants were categorized as obese (63.7%) while the rest of the group was classified as overweight (36.3%). Among the BMI categories selected for this secondary data analysis at baseline (overweight and obesity class I, II and III) the distribution within gender is shown in Table 6. The majority of the females belong to the overweight category 36.7% (182) while among the males the majority belong to the obese class I category 42.9%.

Table 6. Hispanic Adult Selected Participants based on the BMI criteria by gender.

n (%)	Overweight	Obese Class I	Obese Class II	Obese Class III
Female 502 (83.7)	182 (**36.7**)	167 (33.1)	82 (16.7)	71 (13.9)
Male 98 (16.3)	36 (36.3)	42 (**42.9**)	17 (17.3)	3 (3.1)
Total (n=600)	218 (**36.3**)	209 (34.7)	99 (16.8)	74 (12.2)

The selected sample of Hispanic adults that met BMI criterion from the PLMM intervention at baseline had a mean BMI of 32.75 kg/m^2 (SD±5.72). The average BMI among female was 32.91 kg/m^2 (SD±5.91) and 31.92 kg/m^2 (SD±4.55) among male (Figure 3) with no statistical significance differences in t-test (p=0.118).

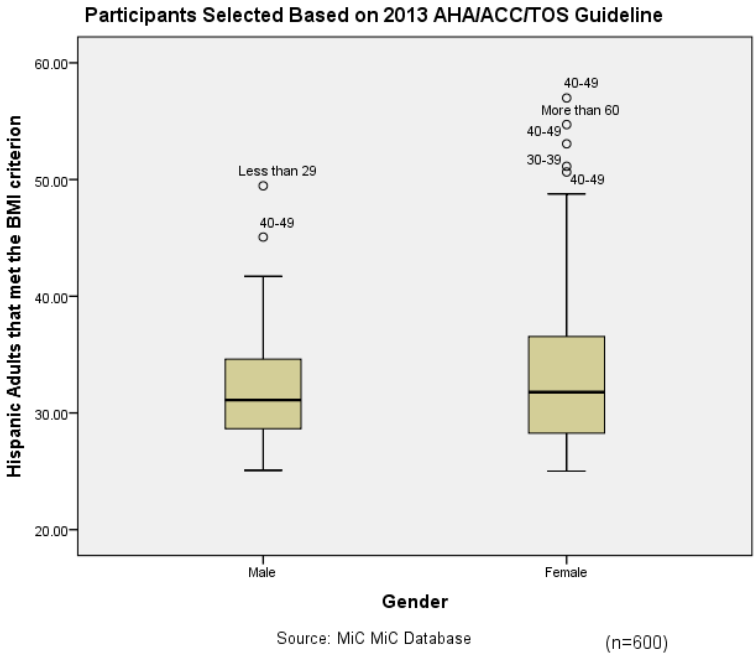

Figure 3. Mean BMI by gender groups among overweight and obese Hispanic adults selected at baseline from the PLMM intervention.

5.3 Specific Aim 2: Identification of Waist Circumference as Risk Factor at Baseline

Specific aim 2 was to identify the WC risk factor (women ≥ 88cm and men ≥ 102 cm) among the selected sample of Hispanic adults upon enrollment in the PLMM intervention and that were also categorized as being overweight or obese. Based on the 2013 Guideline recommendations all participants that were categorized as obese were included in further analysis whether they met or not the WC criterion.

Univariate Analysis were conducted in order to identify overweight and obese participants that met the WC criterion. Among the 600 selected Hispanic adult participants who

were that classified as overweight and obese, a total 80.2% of participants (481) met the WC risk factor (Figure 4).

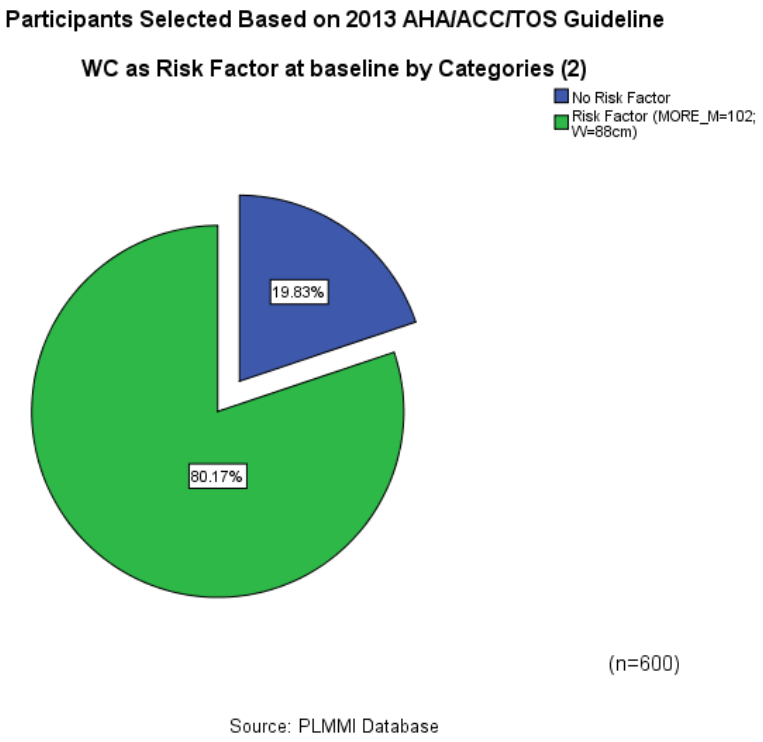

Figure 4. Selected sample of Hispanic adult participants from the PLMM intervention that met the WC risk factor at baseline.

The WC risk factor was absent in 19.8 % the sample of selected participants. Almost 3.2% of those participants that did not met the WC risk factor criterion were obese at baseline; 17 of them belonged to the obese class I category and 2 participants in the obesity class II category (Table 7). Among the selected overweight participants (218) more than half (54.1%) met the WC criterion at baseline shown in Figure 5.

A 16.7% of participants were classified as overweight with no WC as a risk factor; therefore, a total of 100 participants were excluded from further analysis (Figure 5).

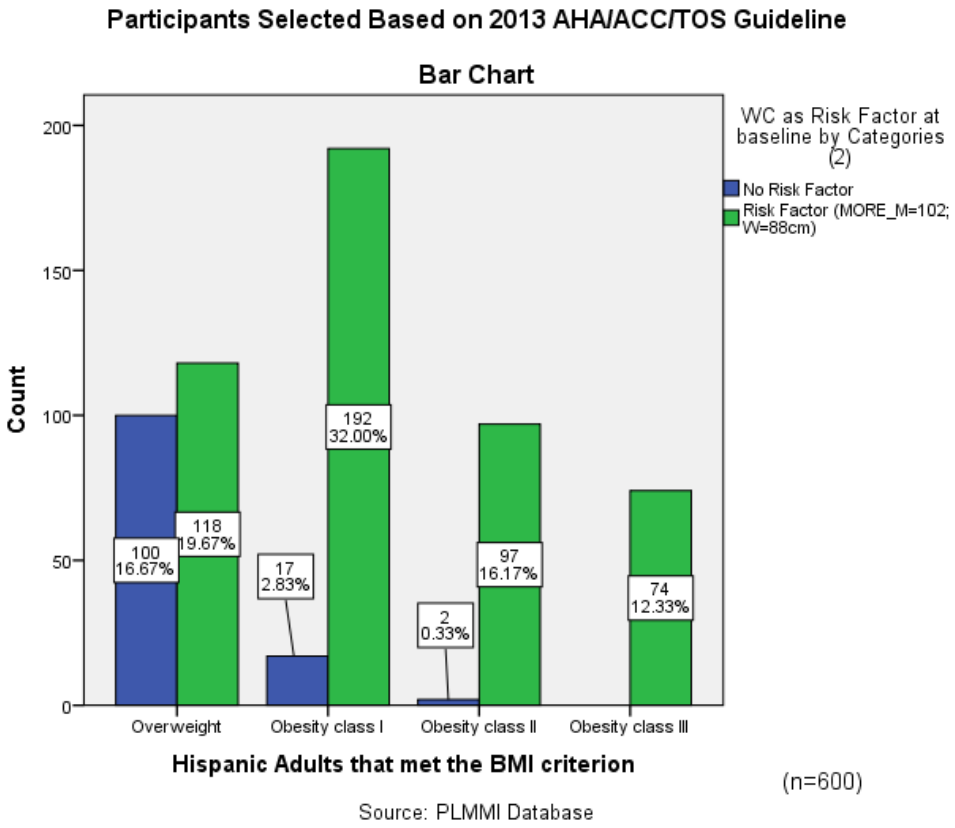

Figure 5. Selected sample of Hispanic adult participants from the PLMM intervention that met the WC risk factor at baseline by BMI categories.

Table 7. Percentages of WC categories of Selected Hispanic adults at baseline.

BMI Categories at Enrollment	**PLMM Participants (N=600)**		**Selected Participants (n=500)**
	No Risk Factor n (%)	**Risk Factor n (%)**	**n (%)**
Overweight	100 (45.9)	118 (54.1)	118 (23.6)
Obesity Class I	17 (8.1)	192 (91.9)	209 (41.8)
Obesity Class II	2 (2)	97 (98)	99 (19.8)
Obesity Class III	-	74 (100)	74 (14.8)
Total	119 (19.8)	481 (80.2)	500 (83.3)

Based on the 2013 AHA/ACC/TOS Guideline a total of 83.3% (500) of Hispanic Adult participants from the PLMM intervention were eligible for weight loss treatment at baseline. The distribution by BMI categories at enrollment is shown in table 7. The selected sample included 118 overweight participants with the WC as risk factor and all 382 obese participants.

Table 8. Hispanic Adult Selected Participants based on the WC criteria by gender.

n (%)	Overweight	Obese Class I	Obese Class II	Obese Class III
Male 69 (13.8)	7 (10.1)	42 (**60.9**)	17 (24.6)	3 (4.3)
Female 431 (84.2)	111 (25.8)	167 (**38.7**)	82 (19.0)	71 (16.5)
Total (n=500)	118 (23.6)	209 (**41.8**)	99 (19.8)	74 (14.8)

The distribution of WC as risk factor by gender was as follows. Among 69 selected males at baseline, 60 had a WC risk factor (≥102cm) and 9 males that belonged into the obese classification did not. Among 431 selected females at baseline, 421 had a WC risk (≥88cm) and 10 women that belonged into the obese classification did not met this criterion. The distribution of the selected participants (n=500) by BMI who met the WC criterion (Table 8) shows that the majority of the selected participants (41.8%) belong into the obese class I category; the distribution by gender shows similar results.

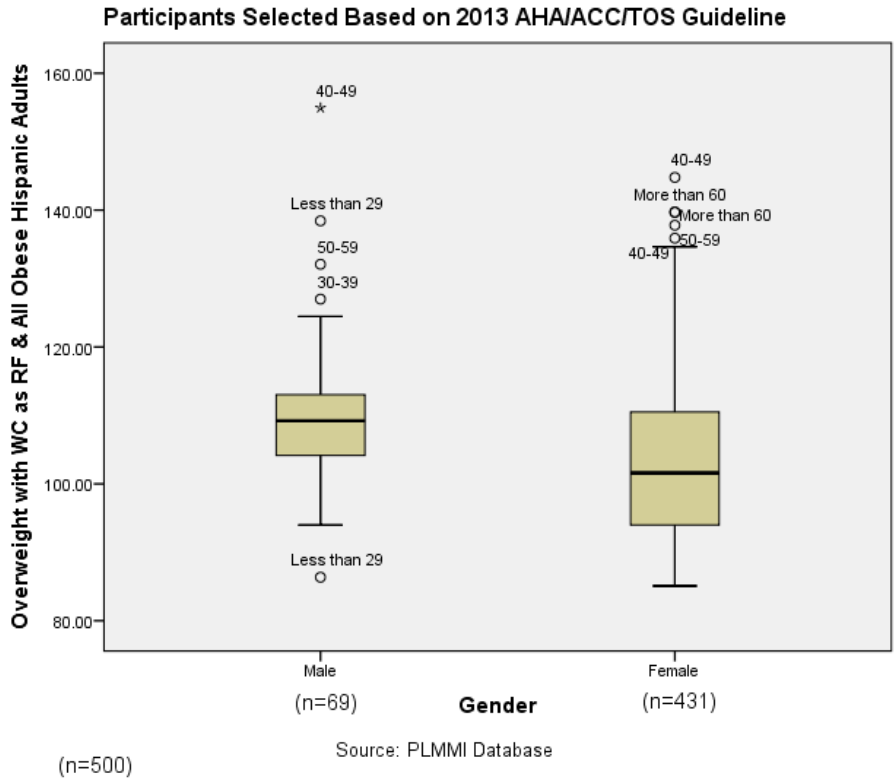

Figure 6. Mean WC by gender among Hispanic adults classified as overweight with WC as risk factor and obese selected from the PLMM intervention at baseline.

Overall the mean WC for all selected participants at baseline (n=500) was 104.26 cm (SD± 11.76); the mean WC was 109.82cm (SD±9.92) among males and 103.37cm (SD±11.80) among females (Figure 6).

5.4 Specific Aim 3: Identification of Weight Loss Post-Intervention

Specific aim 3 was to determine the achievements of the selected participants after the completion of the 4-month PLMM intervention. Among overweight individuals with WC as risk factor and all obese individuals (n=500) that were selected at baseline for this secondary data analysis fifty-seven percent (285) were retained after the 4-month PLMM intervention and completed the follow up assessment. The distribution of the selected participants by gender and by BMI categories are shown in Table 9.

Table 9. Hispanic Adult Selected Participants that Completed the PLMM intervention.

n (%)	**Overweight (n=68)**	**Obesity Class I (n=113)**	**Obesity Class II (n=60)**	**Obesity Class III (n=44)**	**TOTAL (n=285)**
Males	4 (13.8)	4 (13.8)	8 (27.6)	2 (6.9)	29 (10.2)
Females	64 (25.0)	64 (25.0)	52 (20.3)	42 (16.4)	256 (89.8)
TOTAL	68 (23.9)	113 (39.6)	60 (21.1)	44 (15.4)	285 (100)

Among the 285 retained participants, only two-thirds (68.07%) lost weight and 91 (31.93%) individuals gained weight or did not lose any. Among the selected overweight with WC as risk factor and obese participants that were retained after the PLMM intervention, the mean weight at enrollment was 87.11 kg (SD±15.60) and the mean weight after the PLMM intervention was 85.80 kg (SD±15.67). The mean weigh loss among the 285 retained participants after the PLMM intervention was 1.31kg (SD±3.33) and with Pair T-Test (p=0.001) a

statistically significant difference was found (Figure 7). The mean BMI at enrollment among the selected sample was 34.01kg/m^2 (SD±5.30) and after the PLMM intervention was 33.50 kg/m^2 (SD±5.37). The mean BMI difference after the PLMM intervention was 0.51 kg/m^2 (SD±1.29) and with Pair T-Test (p=0.001) a statistically significant difference was found (Figure 8). The mean WC at enrollment was 104.09 cm (SD±11.02) and after the PLMM intervention was 100.76 cm (SD±12.28). The mean WC difference after the PLMM intervention was 3.32 cm (SD±6.38) and with Pair T-Test (p=0.001) a statistically significant difference was found; all three measurements were within a CI 95% (Figure 9).

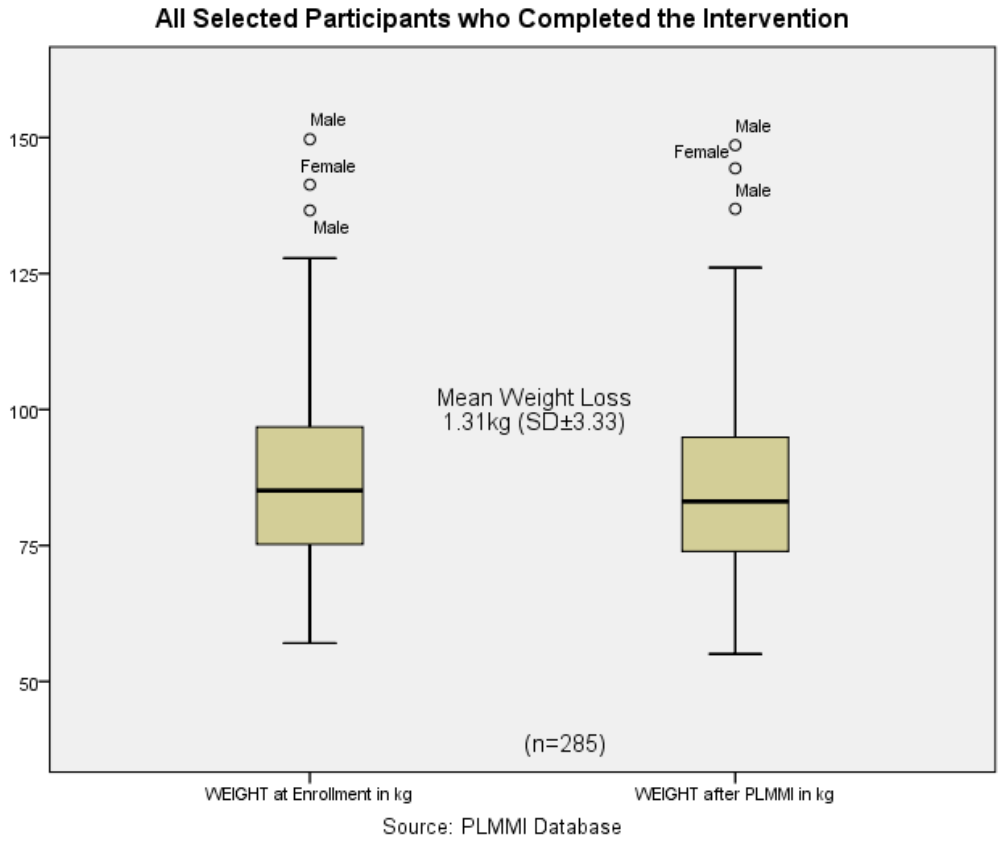

Figure 7. Mean weight among the selected sample of Hispanic adults at baseline and after the PLMM intrevention.

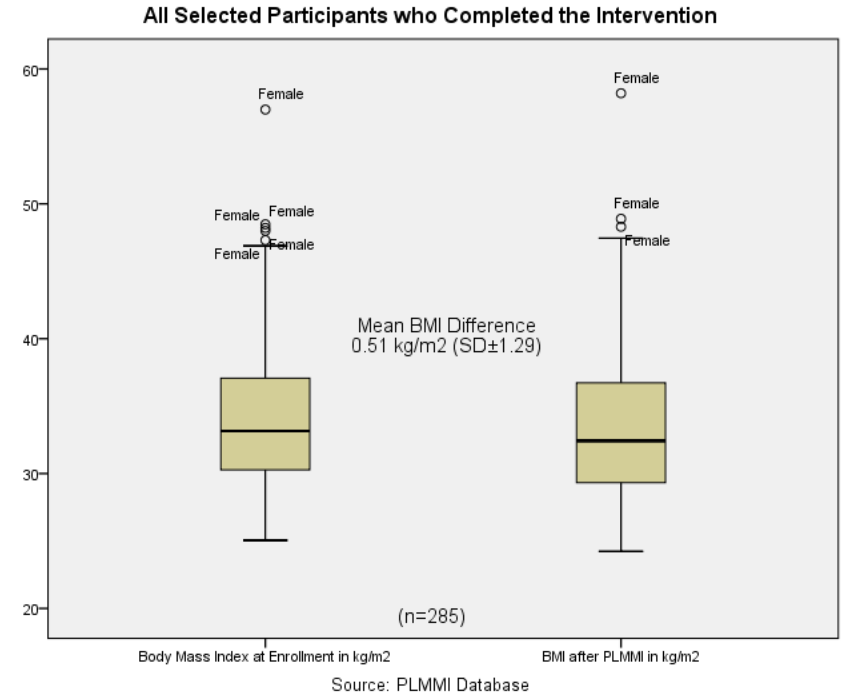

Figure 8. Mean BMI among the selected sample of Hispanic adults at baseline and after the PLMM intrevention.

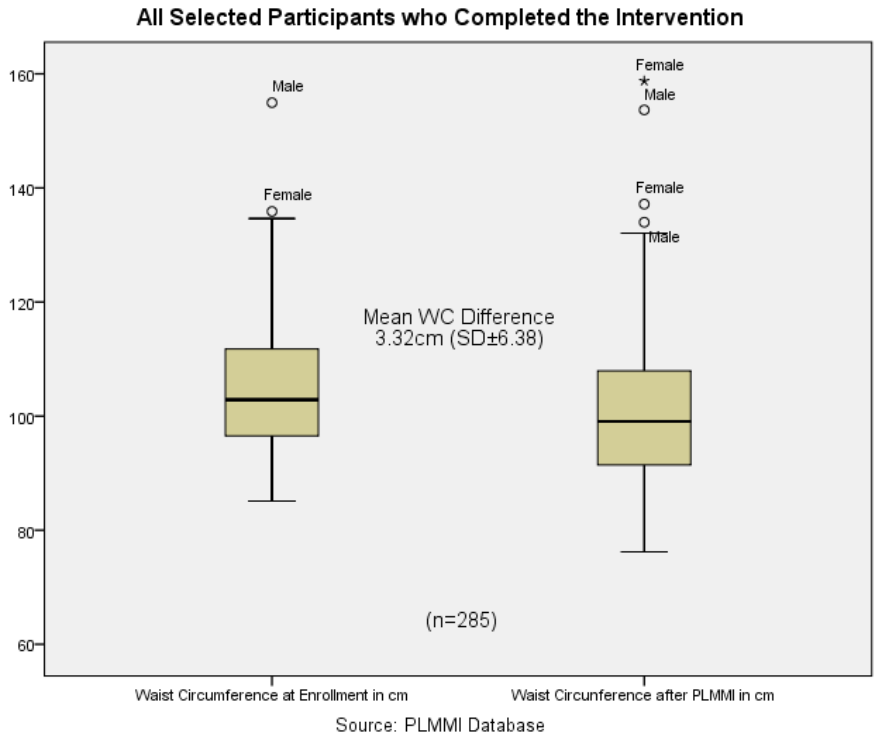

Figure 9. Mean WC among the selected sample of Hispanic adults at baseline and after the PLMM intrevention.

Moreover, the percentage of body weight loss by the selected 285 participants that completed the PLMM intervention in 4-months was 1.48% (SD±3.77). The percentage of body weight loss by BMI categories at enrollment were noticeably greater among those classified as obesity class II with 1.90% (SD±4.34) followed by obesity class I with 1.59% (SD±4.07), obesity class III 1.22% (SD±2.98) and overweight 1.11% (SD±3.22). No statistically significant difference with ANNOVA test (p=0.639) was found among groups (Figure 10).

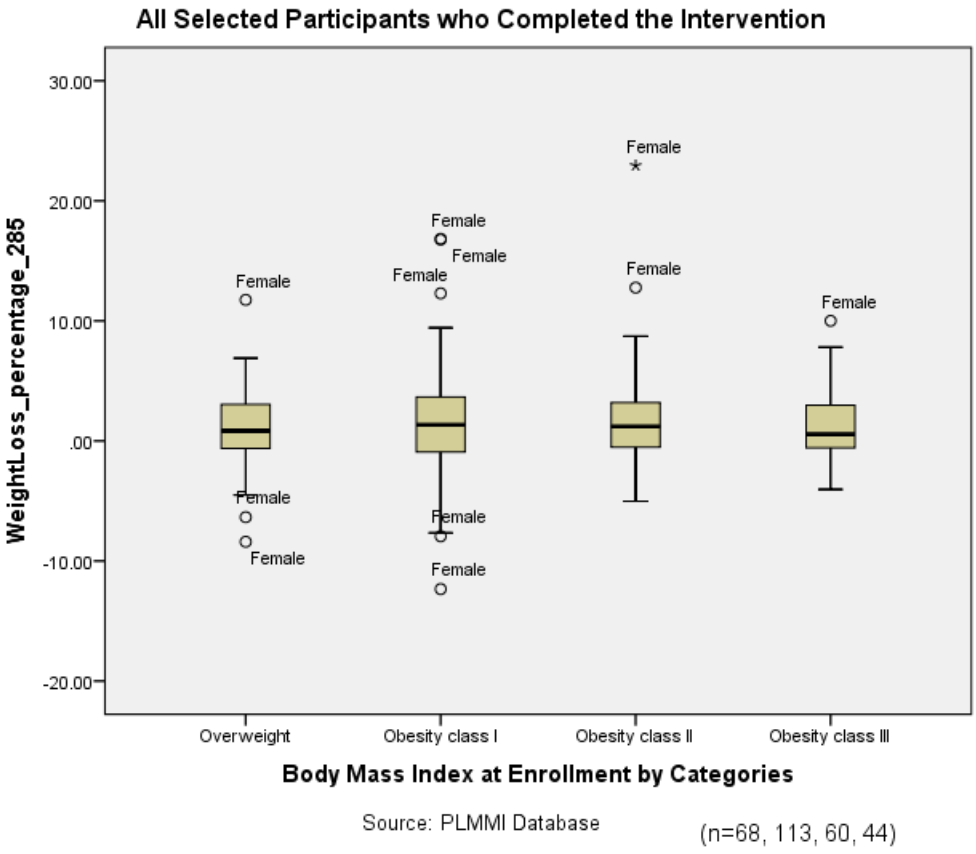

Figure 10. Mean of percent of body weight lost among the selected sample of Hispanic adults after the PLMM intrevention by BMI categories.

The mean weight lost was 1.72kg (SD±2.65) among males and 1.26kg (SD±3.40) among females (Figure 11). Moreover, the percent body weight lost by males was greater 1.81% (SD±2.63) than the percent of 1.44% (SD±3.90) reached among females (Figure 12). No statistically significant difference was found by gender.

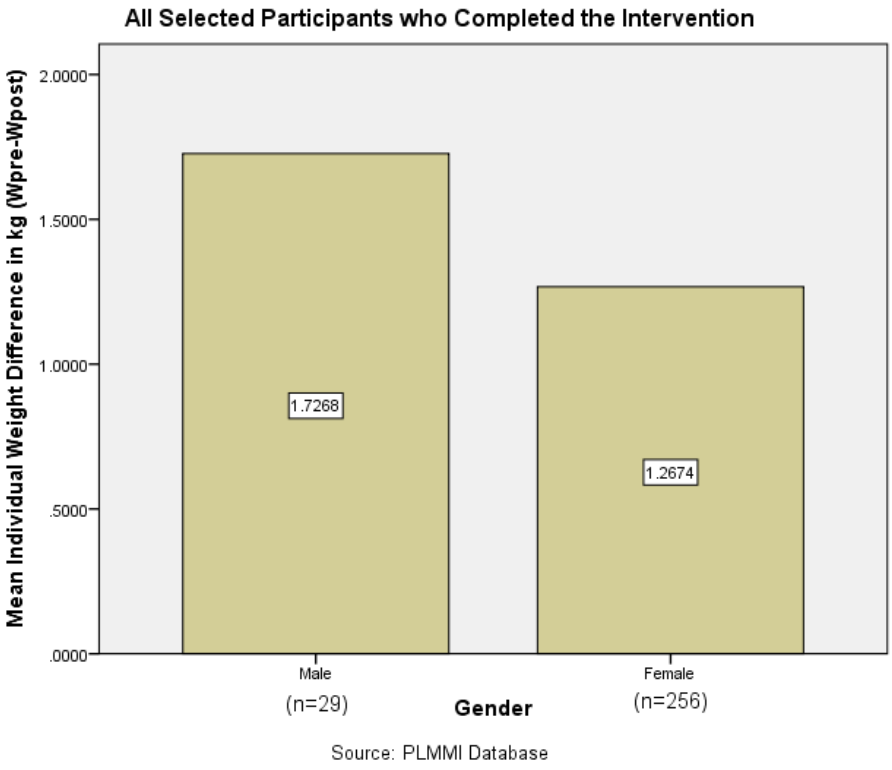

Figure 11. Mean weight loss among the selected sample of Hispanic adults after the PLMM intrevention by gender.

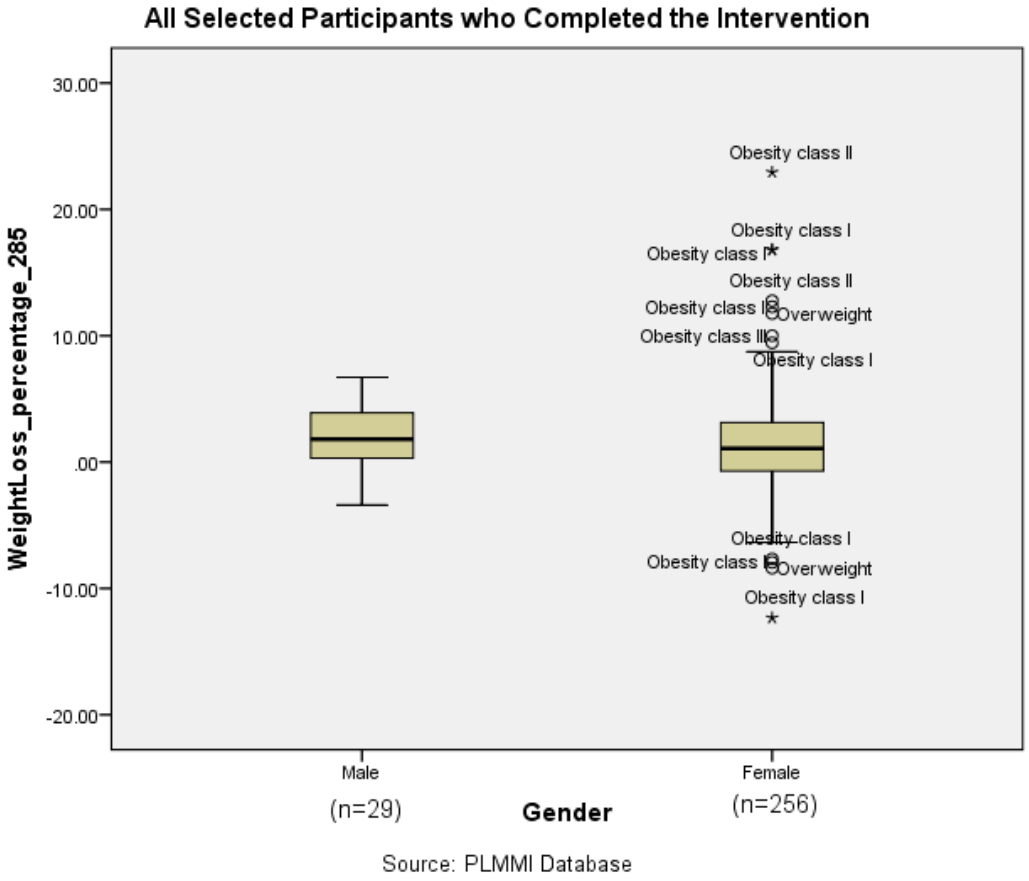

Figure 12. Mean of percent of body weight lost among the selected sample of Hispanic adults after the PLMM intrevention by gender.

The comparison of the changes reached by the selected sample of participants that completed the 4-months PLMM intervention and met the BMI and WC criteria according to the 2013 AHA/ACC/TOS Guideline are shown in Table 10. The clinical measurements of weight, BMI, and WC of the 285 selected participants at baseline, post-intervention and differences were stratified by BMI categories. The obese class II category reached the highest weight loss with 1.77 kg (SD±3.27) followed by the obese class I and obese class II groups with 1.35 kg (SD±3.49) and 1.33 kg (SD±3.35) respectively. Accordingly, the obese grade II category had the

greatest BMI reduction with 0.70 kg/m^2 (SD±1.57) and the greatest WC reduction with 3.67 cm (SD±5.74). Interestingly, the overweight group reached the lowest achievements for weight loss with 0.82 kg (SD±2.30) and a BMI reduction of 0.31 kg/m^2 (SD±0.89) but not for WC with a 3.12 cm (SD±9.29) decrease. The obese class III category reached the lowest reduction in WC with 2.62 cm (SD±4.73). No statistically significant difference was found with ANOVA test at p=0.05 between groups.

Among the selected 285 participants based on the 2013 AHA/ACC/TOS Guideline that completed the 4-months PLMM intervention, a total of 28.1% (80) participants achieved the goal of a 3% weight loss or more. A 4% weight loss goal was reached by 17.2% (49), the 5% goal was achieved by 11.9% (34) and only 2.5% (7) participants achieved the 10% weight loss goal. The table 11 contains the proportion of participants that achieved the weight goal stratified by gender and BMI categories. The obese class I group has the highest proportion (31%) between groups that reached the 3% weight loss. The mean weight loss was explored among the participants that achieved the weight loss goals. Among participants that achieved a 3%, 4%, 5% and 10% goals the mean weight loss was 5.06kg (SD±3.14), 6.4 kg (SD±3.35), 7.46 (SD±3.52) and 13.19kg (SD±3.27) respectively.

Linear regression models were performed (data not shown) to evaluate the correlation between weight loss reduction and the participant's demographics using the variables of gender, age upon enrollment, education and annual income. However, no statistically significant difference was found.

Table 10. Changes in clinical measurements of selected participants that completed the 4-month PLMM intervention by BMI categories (mean±SD).

	Overweight (n=68)	Obese Class I (n=113)	Obese Class II (n=60)	Obese Class III (n=44)	TOTAL (n=285)	p-value
Weight (kg)						
Baseline	71.34±6.99	83.83±9.20	95.08±8.79	109.03±14.25	87.11±15.60	
4-months	70.51±6.92	82.48±9.51	93.31±9.87	107.70±14.52	85.80±15.67	
Diff (B-4)	0.82±2.30*	1.35±3.49*	1.77±3.97*	1.33±3.35*	1.31±3.33	<0.001
BMI (kg/m^2)						
Baseline	28.02±1.35	32.38±1.40	37.01±1.28	43.37±3.13	34.01±5.30	
4-months	27.71±1.54	31.87±1.88	36.30±1.94	42.85±3.50	33.50±5.37	
Diff (B-4)	0.31±0.89*	0.51±1.32*	0.70±1.57*	0.52±1.31*	0.51±1.29	<0.001
WC (cm)						
Baseline	94.73±5.15	100.91±6.85	109.12±8.13	119.82±9.72	104.09±11.02	
4-months	91.60±10.07	97.39±7.65	105.45±8.26	117.18±11.07	100.76±12.28	
Diff (B-4)	3.12±9.29*	3.52±5.03*	3.67±5.74*	2.62±4.73*	3.32±6.38	<0.001
SBP (mmHg)						
Baseline	125.97±17.56	128.74±17.35	131.35±17.42	136.04±21.40	129.75±18.28	
4-months	125.68±18.43	128.66±14.68	132.32±15.62	129.87±14.99	128.91±15.97	
Diff (B-4)	0.28±14.51	0.07±12.26	-0.97±11.46	6.17±14.67*$^+$	0.84±13.20	0.280
DBP (mmHg)						
Baseline	75.64±8.56	77.41±9.33	76.86±9.28	79.65±9.21	77.22±9.16	
4-months	74.55±9.01	77.00±8.77	77.45±8.48	77.70±10.15	76.62±9.02	
Diff (B-4)	1.08±7.36	0.41±6.68	-0.58±7.98	1.94±7.30	0.59±7.23	0.164

* The mean difference is significantly different at the 0.05 level

+ The reported p-value=0.008

Table 11. Achievement of weight loss goal among the selected participants that completed the 4-month PLMM intervention by BMI categories (n, %).

Weight Loss	Overweight (n=68)	Obesity Class I (n=113)	Obesity Class II (n=60)	Obesity Class III (n=44)	TOTAL (n=285)
Goal 3%	**18 (26.5)**	**35 (31.0)**	**16 (26.7)**	**11 (25.0)**	**80 (28.1)**
Male	2 (50.0)	5 (33.3)	2 (25.0)	-	9 (31.0)
Female	16 (25.0)	30 (30.6)	14 (26.9)	11 (26.2)	71 (27.7)
Goal 4%	**10 (14.7)**	**21 (18.6)**	**12 (20.0)**	**6 (13.6)**	**49 (17.2)**
Male	1 (25.0)	4 (26.7)	2 (25.0)	-	7 (24.1)
Female	9 (14.1)	17 (17.3)	10 (19.2)	6 (14.3)	42 (16.4)
Goal 5%	**6 (8.8)**	**15 (13.3)**	**9 (15.0)**	**4 (9.1)**	**34 (11.9)**
Male	1 (25.0)	3 (20.0)	-	-	4 (13.8)
Female	5 (7.8)	12 (12.2)	9 (17.3)	4 (9.5)	30 (11.7)
Goal 10%	**1 (1.5)**	**3 (2.7)**	**2 (3.3)**	**1 (2.3)**	**7 (2.5)**
Male	-	-	-	-	-
Female	1 (1.6)	3 (3.1)	2 (3.8)	1 (2.4)	7 (2.5)

5.5 Specific Aim 4: Identification of Blood Pressure Changes Post-Intervention

Specific aim 4 was to identify blood pressure changes among the selected Hispanic adults who were selected according to the 2013AHA/ACC/TOS Guidelines at baseline and completed the 4-months follow up of the PLMM intervention. Among the overweight individuals with WC as risk factor and obese individuals that were selected at baseline from the PLMM intervention for further analysis (n=500), as mentioned before, 285 (57.0%) were retained and completed the 4-month follow up.

Regarding SBP, almost half of the individuals (49.1%) had a reduction in blood pressure. On the other hand, 145 individuals did not had a reduction or presented an increase in SBP. In the case of DBP, more than half of the selected participants (55.4%) had a reduction and 127 individuals had an increase in DBP or did not had a reduction. Among the 285 retained participants, the mean systolic blood pressure at enrollment was 129.97 mmHg (SD±18.28) and after the PLMM intervention was 128.91 mmHg (SD±15.97). The reduction in SBP was 0.84 mmHg (SD±13.20) and there was no statistically significant difference with paired t-Test (p=0.280) (Figure 13). The mean DBP at enrollment was 77.22 mmHg (SD±9.16) and after the PLMM intervention was 76.62 mmHg (SD±9.02). The reduction in DBP was 0.59 mmHg (SD±7.23) and there was no statistically significant difference with paired t-Test (p=0.164) (Figure 14).

However, the reduction in SBP by the selected sample of 285 participants by BMI categories at enrollment were significantly greater among those classified as obesity class III (Table 9) with a reduction of 6.17mmHg (SD±14.67).

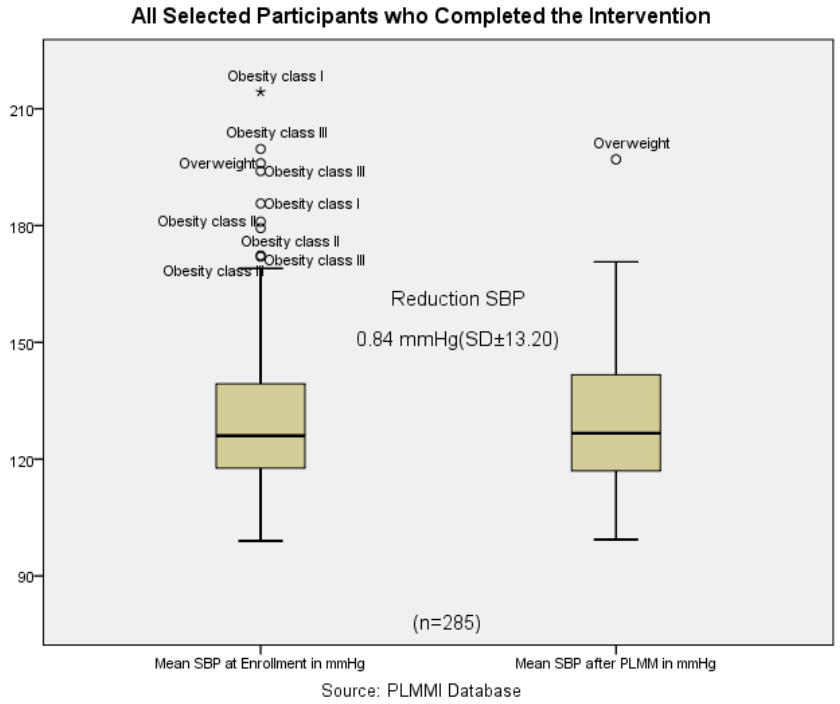

Figure 13. Mean SBP among the selected sample of Hispanic adults at baseline and after the PLMM intrevention.

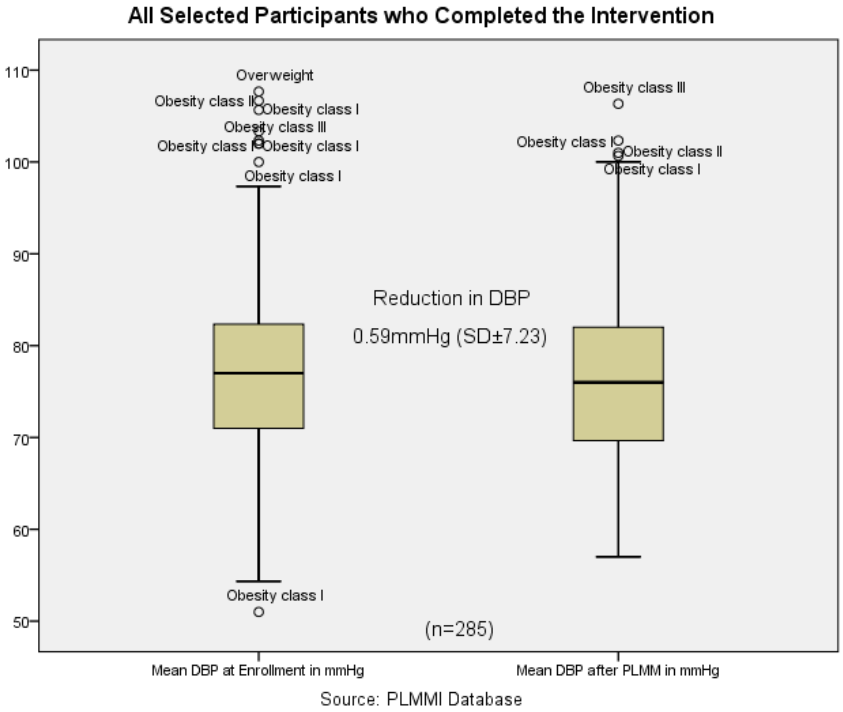

Figure 14. Mean DBP among the selected sample of Hispanic adults at baseline and after the PLMM intrevention.

The SBP reduction in the overweight category was 0.28 mmHg (SD±14.51) while the obesity class I group had a 0.07 mmHg (SD±12.26) reduction. The obesity class II group reported a mean reduction of -0.97 mmHg (SD±11.46) (Figure 15). The ANNOVA test shows statistically significant difference (p=0.031) between the reduction reached among BMI groups. The post hoc Bonferroni test shows that the reduction reached by the obesity class III group after the PLMM intervention was statistically significant difference when compared to obesity class II (p=0.037) and nearly significant when compared to Obesity class I (p=0.054); however, no difference was found with the overweight category (p= 0.124).

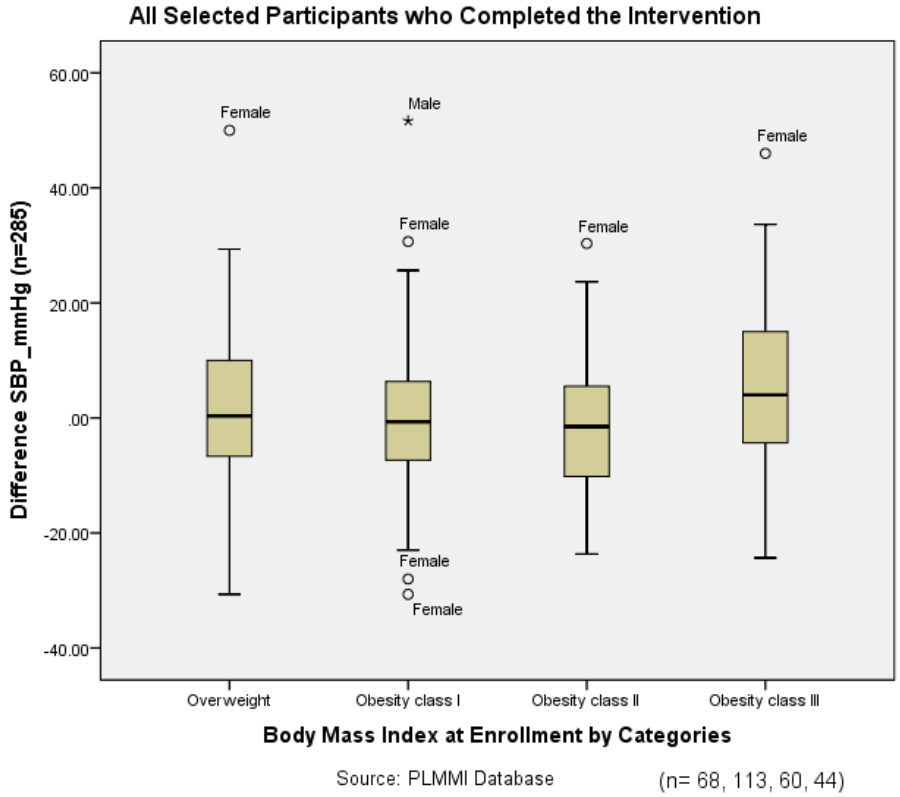

Figure 15. Mean SBP among the selected sample of Hispanic adults after the PLMM intrevention by BMI categories.

The reduction in DBP by the selected 285 participants by BMI categories at enrollment were visibly greater among those classified as obesity class III with a reduction of 1.94 mmHg (SD±7.307). The reduction in DBP among the overweight category was 1.08 mmHg (SD±7.36) and for class I obesity 0.41 mmHg (SD±6.68). The obesity class II category report a negative mean of -0.58 mmHg (SD±7.98). The ANNOVA test did not shows statistically significant difference between the reductions reached on DBP among BMI categories (Figure 16).

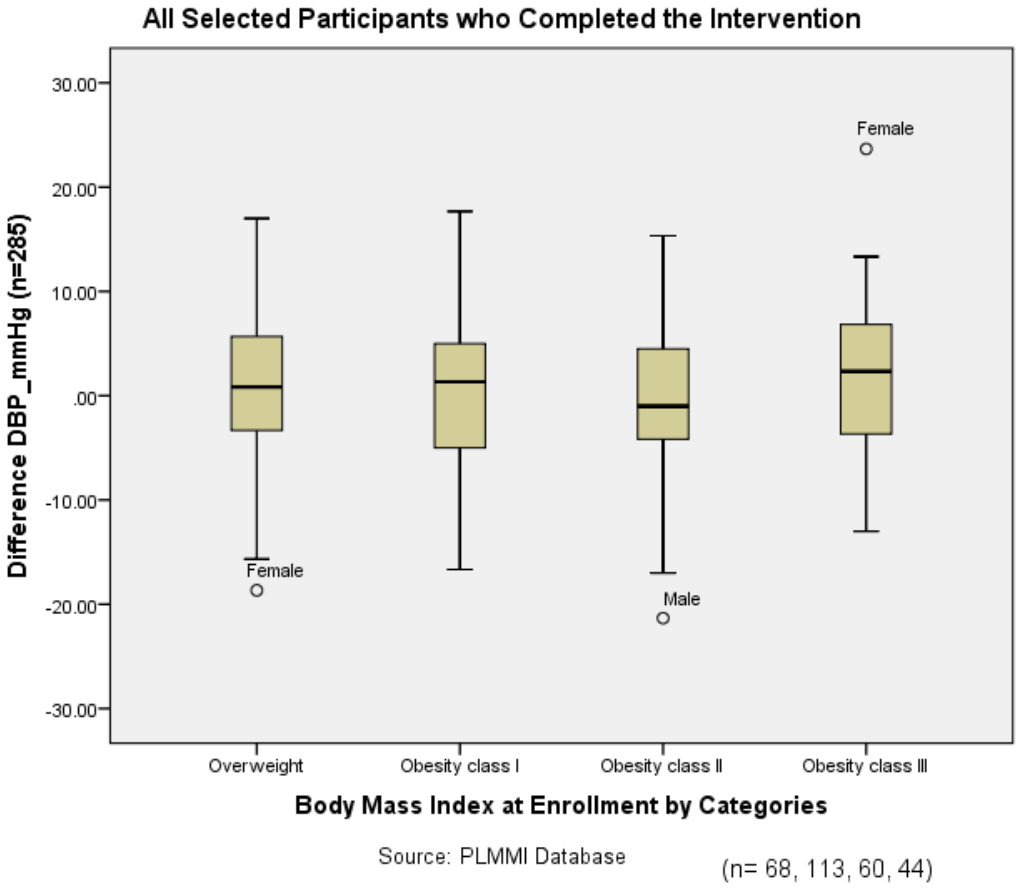

Figure 16. Mean DBP among the selected sample of Hispanic adults after the PLMM intrevention by BMI categories.

The reduction in BP by gender was explored and these results are shown in Figures 17 & 18. Among the selected 29 males, the mean reduction in SBP was 0.51mmHg (SD±14.09) while the mean reduction in DBP was 0.29 mmHg (SD±8.65). Among the selected 256 females, the mean reduction in SBP was 0.88mmHg (SD±13.12) and mean reduction in DBP was 0.63mmHg (SD±7.08). There was no significant difference between mean ranks for females (143.84) and males (135.55) with Mann-Whitney test for SBP (p=0.608); nor either for DBP (p=0.992) between females (mean rank= 143.02) and males (mean rank= 142.86).

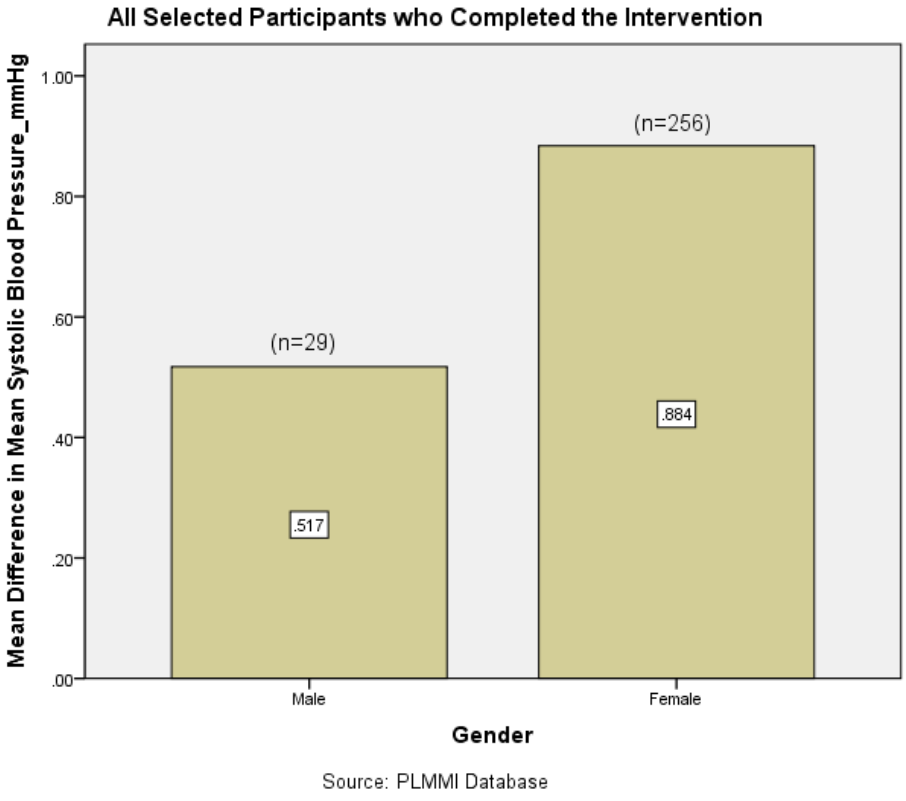

Figure 17. Reduction in SBP among the selected sample of Hispanic adults after the PLMM intrevention by gender categories.

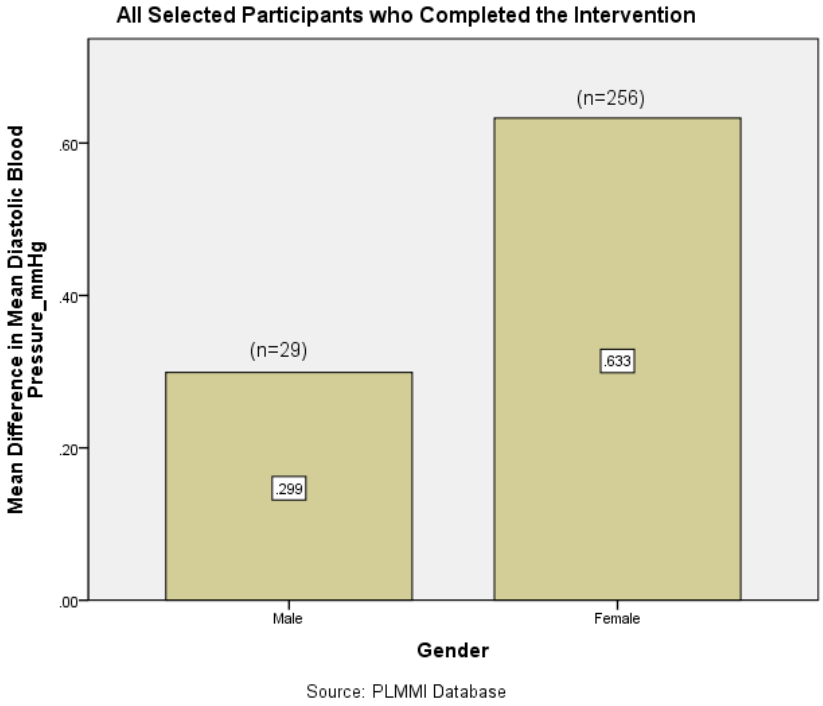

Figure 18. Reduction in DBP among the selected sample of Hispanic adults after the PLMM intrevention by gender categories.

Among the 285 selected participants based on the 2013 AHA/ACC/TOS Guideline that completed the PLMM intervention, a total of 42.1% (120) participants had a clinically significant reduction of 3 mmHg on SBP (Table 12). The clinically significant reduction of 2 mmHg on DBP was reached by 45.3 % (129) participants. The majority of participants belonging to the obesity class II had clinically significant reduction in SBP and DBP (Table 10). No statistically significant difference was found between BMI groups with Pearson Chi-Square test at p-value 0.05. Linear regression models were performed (data not shown) to evaluate the correlation between changes in SBP and DBP and the participant's demographic information using the variables of gender, age upon enrollment, education and annual income. However, no statistically significant difference was found.

Table 12. Clinically significant blood pressure reduction achievement after the 4-month PLMM intervention by BMI categories 3 mmHg reduction in SBP and 2 mmHg reduction in DBP (n, %).

Blood Pressure	Overweight (n=68)	Obesity Class I (n=113)	Obesity Class II (n=60)	Obesity Class III (n=44)	TOTAL (n=285)
SBP ≥3mmHg	30 (44.1)	44 (38.9)	22 (36.7)	24 (**54.5**)	120 (42.1)
Males	4 (100)	3 (20.0)	1 (50.0)	1 (50.0)	9 (31.0)
Females	26 (40.6)	41 (40.6)	21 (40.4)	23 (54.8)	111 (43.4)
DBP ≥2mmHg	32 (47.1)	59 (52.2)	19 (31.7)	24 (**54.5**)	129 (45.3)
Males	3 (75.0)	9 (60.0)	1 (12.5)	1 (50.0)	14 (48.3)
Females	29 (45.3)	45 (45.9)	18 (34.6)	23 (54.8)	115 (44.9)

CHAPTER 6: DISCUSSION

The 2013 AHA/ACC/TOS Guideline is based on strong scientific evidence and serves as a reference for health providers to overcome obesity and its related chronic diseases. By using the 2013 AHA/ACC/TOS Guideline to select the data from Hispanic obese and overweight with large WC as risk factor from the PLMM participants, the intervention showed much better results than programs that only use regular weight loss information sessions with their patients. Wadden and colleagues reported a decrease of 0.7% of body weight in patients who were followed for one year and participated in weight loss information sessions, however this program did not include behavioral strategies (Wadden et al., 2009); while the current study showed that a lifestyle intervention led by CHW/PS resulted in 1.48 % weight loss in a 4-month period.

The 2013 AHA/ACC/TOS Guideline reported the need to understand and improve the efficiency of on-site lifestyle interventions on key populations including racial/ethnic groups. The results from this study show that the recommendations provided by the 2013 AHA/ACC/TOS Guideline are valid for Hispanics living in the U.S. Mexico border region. The results showed that from the selected sample of Hispanic participants that completed (n=285) the PLMM intervention 68% participants lost weight. Similar results were found by the Look AHEAD intervention study, in where a population with diabetes that included minorities (n=5145), reported that 62% of their subjects lost weight (Wing et al., 2011). Interestingly, a yearlong lifestyle intervention on patients with at risk for diabetes reported that participants that completed the intervention had 44% lower diabetes incidence even if they did not meet the weight lost goal of 7% (Hamman et al., 2006). The study by Hamman and collaborators (2006) showed that almost 38% of participants did not lose weight, thus suggesting that even when the

weight loss is modest or non-existent, the physical activity included in a lifestyle intervention can result in beneficial health outcomes.

The percentage of body weight loss by BMI categories was noticeably greater among those classified as obesity class II with 1.90% (SD±4.34) followed by obesity class I with 1.59% (SD±4.07) and overweight 1.11% (SD±3.22). The same trend was observed in lifestyle interventions with Caucasian adults in where participants with class II obesity lost more weight than those who were classified as class I and overweight (Barte, Veldwijk, Teixeira, Sacks, & Bemelmans, 2014). Almost half of participants selected according to the 2013 AHA/ACC/TOS Guidelines showed positive changes in blood pressure, which have been associated with decreased risk for CVD and mortality in previous studies (Vasan et al., 2001).

The results showed that 19 obese participants did not present the risk factor of large WC. On an individual basis, it is important to recognize that BMI is a measure of body weight rather than excess body fat that is why this indicator is used as a screening tool rather than a diagnostic tool (CDC, 2013). Review committees have selected the WC measurement as an accurate indicator of other individual and multiple cardiovascular risk factors, hence a measure for indicating the need for weight management (Dobbelsteyn, Joffres, MacLean, & Flowerdew, 2001; Lean, Han, & Morrison, 1995). The weight losses after the 4-month intervention yielded a statistically significant mean WC reduction of 3.32 cm. Similarly, The Look AHEAD intensive lifestyle intervention reported a 6.2 cm WC reduction while the control group in the same study showed a 0.5 cm reduction after 1 year (Espeland, 2007).

There was no statistically significant difference in BP after the 4-month intervention. However, a noteworthy observation from the study was a decrease in BP trend in both, SBP and DBP. Meta-analysis studies report that six months is the weight loss zenith for interventions,

except for bariatric surgery (Espeland, 2007; Perri, Nezu, Patti, & McCann, 1989; Yanovski & Yanovski, 2002; Jensen et al., 2013). It is inferred that a longer intervention would result in more meaningful decreasing BP trends same that can result into a statistically significant change. Although the mean BP in this study was not statistically significant, 42.1% (120) participants achieved a clinically significant reduction of 3 mmHg or more, as suggested by literature (Jensen et al., 2013). Furthermore, the obesity class III group from the current study had a significant SBP reduction of 6.17 mmHg.

Lastly, the 2013 AHA/ACC/TOS Guidelines state the need to determine the adequate skills and personal characteristics required to serve in a lifestyle intervention. Browstein and collaborators (2007) propose that Community Health Workers can bridge the social and cultural gaps between the health providers and the community; henceforth, aiding to a successful implementation of community based interventions. The positive results of the study suggest that for the Hispanic community living in the border region, Community Health Workers/Promotores de Salud possess the personal characteristics to serve as lifestyle interventionists.

CHAPTER 7: CONCLUSSION

In conclusion, by applying the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults to a Hispanic population that engaged in the PLMM intervention it was confirmed that this type of comprehensive intervention offers an efficient method to manage overweight and obesity among Hispanic adults living in the U.S.-Mexico border region. The 4-month PLMM intervention demonstrated much better results than programs that only provide informational weight loss sessions for their patients. The participants that completed the intervention showed a statistically significant decrease in weight, BMI, and WC. Other interventions such as the Look AHEAD study have achieved improved results in terms of weight loss (Wadden et al., 2009). However, when taking into consideration that such studies have been implemented for at least 3 times the duration of the present study, one can assume that the PLMM intervention has the potential to improve the health status of participants should the intervention were to last for a longer period of time and when a diet component is included. Community Health Workers or Promotores de Salud play an important role in comprehensive lifestyle intervention programs that include multiple components (heart-health education, nutrition education and a variety of physical activities) such as the PLMM intervention.

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CURRICULUM VITAE

Silvia Salinas Lopez was born in Mexico D.F, and raised in Chihuahua, Mexico. Silvia graduated from the Autonomous University of Chihuahua (UACH) with a medical degree as general practitioner in the summer of 2006. In the fall of 2012, Silvia was accepted in the Master of Public Health Program at UTEP's Department of Public Health Sciences. While attending graduate school, Silvia worked as a teaching assistant for the Department of Public Health and Volunteer as a graduate research assistant in the collaborative study "Developing an educational intervention for Hispanic women with Gestational Diabetes Mellitus (GDM) in El Paso, Texas." In the summer of 2014, Silvia was awarded with the Directors of Health Promotion and Education (DHPE) Summer Internship Program for Public Health while doing her intership at El Paso First Health Plans Inc. In the summer of 2013 she was awarded with the "Provost's summer student research award" while working in the "Association of Physical Activity, Obesity, and Carotid Intima-Media Thickness (cIMT) among School children in Urban Neighborhoods in Ecuador" study P.I. Margaret M. Weigel, Ph.D. Silvia worked under Dr. Duarte-Gardea's mentorship and her thesis explored the efectiveness of the PLMM intervention among Hispanic adults living in El Paso, Texas. She will continue her academic career in the Doctoral Program of Interdisciplinary Health Science at UTEP where she has been accepted for the Fall 2016 cohort and received a Graduate Research Associate position.