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The National Diabetes Prevention Program an intervention for Diabetes Risk Reduction

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THE NATIONAL DIABETES PREVENTION PROGRAM AN
INTERVENTION FOR DIABETES RISK REDUCTION

By

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A thesis submitted in partial fulfillment
of the requirements for the

Master of Public Health

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Abstract

Diabetes mellitus is among the most frequently occurring chronic conditions, affecting 28 million adults in the Nation. The Nevada diabetes prevalence rate is approaching the National average, with 1 out of 4 diabetic patients experiencing serious clinical complications. Diabetes is typically preceded by a preventable condition classified as prediabetes, in which the blood sugar level exceeds the normal level, yet not enough to be classified as Type 2 diabetes. Prediabetes increases the risk of developing diabetes within 10 years, if not effectively managed. In an attempt to help reduce this risk, the CDC recently introduced an evidence-based intervention, the National Diabetes Prevention Program (NDPP) that aims to delay the onset of diabetes mellitus in people having prediabetes or those predisposed to having diabetes mellitus. The purpose of this current study is to assess the effect of the NDPP upon the change in weight and physical activity status of participants. A total of 66 subjects were recruited from the employees of Wyndham vacation resort, United Healthcare, and center of the Dignity Health organization, following the selection criteria provided by the CDC. This study assessed the secondary data obtained from the Women's Center of Dignity Health. The study utilized multiple logistic and linear regression, pearson's correlation, and one way ANOVA for assessing the association, and group differences among the variables used. The results of the logistic regression indicated that the odds of achieving the desired weight loss goal is 24% more likely for each additional session attended in the intervention. Moreover, the linear regression model suggested that number of sessions significantly predict the physical activity minutes achieved and percentage of weight loss. It was also determined that for every increase in session, there will be an increase in physical activity minutes of 8.3 minutes and decrease in weight by 0.3 % from the baseline.

The findings of this study may suggest an effective intervention for regulating the modifiable risk factors for lowering the risk of diabetes mellitus. In addition, this study may propose an avenue of prospective research for ascertaining sustainability of behavior change and performing outcome evaluation of the program among future intervention participants.

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Introduction

Type 2 diabetes mellitus comprises a collection of various dysfunctions that are characterized by the presence of hyperglycemia, which occurs as a result of a combination of factors such as insulin action resistance, inappropriate or excessive secretion of glucagon, and insufficient secretion of insulin. With Type 2 diabetes mellitus, the body is either resistant to the effects of insulin, or the body does not produce sufficient insulin in order to maintain a normal level of glucose. Some of the most classical symptoms of Type 2 diabetes mellitus include: increased frequency of urination, excessive thirst, and increased appetite, weight loss because of the inability of the body to metabolize glucose resulting in the body using alternative fuels kept in fat and muscle, and fatigue due to body cells being deprived of sugar making the body feel irritated and exhausted.

Diabetes mellitus is often preceded by a preventable condition called prediabetes, in which the level of blood sugar in the body is higher than the normal level, but not high enough to be classified or considered as a full-blown type 2 diabetes (Tabak, Herder, Rathmann, Brunner, & Kivimaki, 2012). Being asymptomatic, prediabetes tends to remain undiagnosed for many years till it turns into a full-blown diabetes mellitus. Individuals with prediabetes stand a high risk of developing type 2 diabetes within 10 years unless they embrace a healthier lifestyle, such as getting involved in more physical exercises and losing weight. Prediabetes diagnostic criteria have altered over time and generally vary depending upon the institution of origin.

Background

Diabetes mellitus is among the most frequently occurring chronic condition in the United States (Center for Disease Control and Prevention [CDC], 2015). According to the National Diabetes Statistic Report by CDC (2014), there are over 20 million people (9.2% of the population) with confirmed diabetes mellitus, in the United States. The prevalence (burden) of diabetes has increased significantly from 5.5 to 20.8 per 100 population, over the past years (CDC, 2014). Diabetes mellitus is invariably associated with other complications such as kidney failure, retinal disorders, and nerve degeneration that may decrease the quality of life at the individual level (CDC, 2015). Diabetes is a major risk factor for cardiovascular diseases such as heart attack and stroke. It has been previously estimated that diabetic patients are 1.7 times more likely to die from cardiovascular diseases as compared to the non-diabetic individuals (CDC, 2014). Moreover, diabetic patients are 1.5 times more likely to be hospitalized for stroke and heart attacks as compared to their non-diabetic counterparts (CDC, 2014). Additionally, diabetes patients tend to have greater health care expenditure (nearly 2.5 times) as compared to the normal population (CDC, 2014). Currently, at the National level, diabetes has substantially raised the health care cost nearly over \$2 billion in the United States (CDC, 2015). At the State level, especially in Nevada, the prevalence rates are comparable to the national rate. In 2011, the prevalence rate of diabetes in Nevada was 10 per 100 population as compared to U.S rate of 9.5 per 100 population (CDC, 2014). Among various counties in Nevada, the prevalence of Type 2 diabetes, is the highest in Clark & Churchill County (CDC, 2014).

Literature Review

Based on World Health Organization data, people are believed to be at high risk of progressing into type 2 diabetes mellitus if they are in one of the following two conditions. The first one is impaired fasting glucose (IFG), which is a condition whereby the fasting blood glucose level is raised consistently above normal concentration levels (6.1 mmol/L - < 7.0 mmol/L) (Tabak, Herder, Rathmann, Brunner, & Kivimaki, 2012). The second is impaired glucose tolerance (IGT), which is defined as a pre-diabetic condition of hyperglycemia related to resistance of insulin as well as the increased possibility of cardiovascular pathology. With IGT, the concentration of FPG is at the level of <7.0 mmol/L with a 2 h post load plasma glucose concentration of ≥ 7.8 as well as <11.1 mmol/L, as measured through a 75 g oral glucose tolerance test (OGTT) (Tabak et al., 2012). Additionally, a new category for high risk diabetes has been introduced; glycated hemoglobin A1C (HbA1c) 5.7 - 6.4% (Tabak et al, 2012). Approximately 5-10% of pre-diabetic people become diabetic annually. Notably, the number of diabetic patients has become triple over the period of thirty years from 1980 – 2011(CDC, 2013). This rate of conversion varies according to population characteristics as well as definitions of prediabetes (Forouhi, Luan, Hennings, & Wareham, 2007). In one meta-analysis research of diabetes progression studies published in the period between 1979 and 2004, annual rates of diabetes incidences in people with isolated IGT (4–6%) or those with isolated IFG (6–9%) were found to be lower than in patients with both IFG and IGT (15–19%) (Gerstein, Santaguida, & Raina, et al., 2007). Next, in subsequent major diabetic studies, the estimates of progression have been similar – the yearly incidence was 11% in the DPP (Diabetes Prevention Program) outcomes study, 6% in patients with IFG within the US Multi-Ethnic Study of Atherosclerosis, as well as 9% in patients with IFG along with 7% in patients with

HbA1c 5.7–6.4% as found in a major Japanese population-based research (Diabetes Prevention Program Research Group, 2009; Yeboah et al., 2011; Heianza et al., 2011). Research studies suggest the risks of diabetes development on the ground of FPG along with 2h post load glucose and the one defined by HbA1c concentration are similar (Zhang, Gregg, & Williamson, et al., 2010). The ADA expert panel assessed the number of individuals with prediabetes who are likely to develop diabetes as 70% (Tabak et al., 2012). Diabetes mellitus is associated with various risk factors. In addition, the transformation of prediabetes into diabetes mellitus varies across different ethnic and age groups.

Risk factors for both prediabetes and type 2 diabetes are as follows: being aged 45+, being obese or overweight, having a history of diabetes in the family, belonging to an ethnic minority (African or Asian American, American Indian, Hispanic, or Pacific Islander), having a gestational diabetes history, and being physically inactive (less than 3 times a week) (YanFeng, Geiss, Burrows, & Rolka, 2013; Vojta, De Sa, Prospect, & Stevens, 2012). According to the CDC's report on chronic diseases (2015), lack of physical activity and poor nutrition are among the unhealthiest behaviors that contribute significantly to chronic conditions resulting in early morbidity and mortality. According to the Nurse Health Study, (1992-1998), physical inactivity is a risk factor for both obesity as well as type 2 diabetes mellitus (Hu et. al., 2003). Also, obesity (commonly expressed as body mass index [BMI] ≥ 30), is a major risk factor for developing type 2 diabetes mellitus. Previous studies have showed a strong association between increased BMI and risk of diabetes mellitus (Ganz et. al., 2014). People having BMI $> 40 \text{ Kg/m}^2$, are 11 times more likely to be diagnosed with type 2 diabetes mellitus as compared to those having normal BMI ($\leq 24 \text{ Kg/m}^2$) (Ganz et. al., 2014).

Also, the risk of obesity and type 2 diabetes mellitus varies depending upon the type of sedentary behavior such as increased TV watching and increased sitting in the workplace (Hu et. al., 2003). The risk of obesity quadruples in people who engaged in prolonged TV watching as compared to those who sit for a long period at their work place (Hu et. al., 2003). Furthermore, some previous studies also determined the impact of increasing weight on the risk of type 2 diabetes mellitus across different ethnic backgrounds (Shai et. al., 2006). According to Shai et.al (2006), with each 5 kg increase in weight, the risk of diabetes mellitus is the greatest (84%) among the Asians, followed by Hispanics (44%), blacks (38%), and whites (37%). Weight gain tends to cause the differential negative effects among Asians (Shai et. al., 2006). On the contrary, healthy, low fat diets including more fiber content have a more protective effect among Asians as compared to whites (Shai et. al., 2006).

Researchers have also pointed out that the increased incidence of type 2 diabetes mellitus is due to the inability to correctly capture the reversible and preventable prediabetes in order to prevent its progression to diabetes mellitus. There are various barriers for correctly diagnosing prediabetes. The first barrier for correctly diagnosing diabetes and prediabetes is discrepant diagnostic criteria. In particular, diagnostic techniques for identification of people at risk include glucose (fasting as well as OGTT) and HbA1c measurements. Modern diagnostic modalities can often be discrepant since they might identify different populations at risk of developing diabetes depending on whether the diagnosis is based on glucose or glycosylated hemoglobin. These considerations get further complicated by varied criteria for screening and diagnosis of prediabetes and diabetes provided by the American Diabetes Association and the WHO. Also, prediabetes definitions differ, so that the incidence of HbA1c 6.0–6.4 % possibly identifies people at lower risk in comparison with other criteria (Bergman et al., 2012).

Another barrier for correctly diagnosing prediabetes is physicians' lack of knowledge of how to correctly assess prediabetes. In other words, "Physicians do not know how to diagnose prediabetes." It has also been found that physicians are reluctant to research even easily accessible information (Zefferino, 2007). Doctors have recommended that weight reduction and increased frequency of physical activities can significantly help in lowering the risk of developing diabetes mellitus.

During the last decade, high reputable randomized studies have unequivocally confirmed that diabetes mellitus can be effectively prevented or delayed by programs directed at lifestyle modification in people who are at risk of diabetes development (Bergman, 2013). The Americans with Diabetes Act (ADA), the European Association for the Study of Diabetes (EASD), and Diabetes UK all provide diabetes prevention guidelines within their nutritional recommendations. The ADA emphasizes that the risk of diabetes development reduces if individuals engage in lifestyle changes, including reduced energy and fat intake, education, and regular physical activity (Bantle & Slama, 2006). The EASD see weight loss as the critical component of lifestyle modification in overweight individuals. They advise that the appropriate macronutrient composition of the person's diet containing overall fat, is less than 30% of whole energy intake, saturated fat, less than 10%, and intake of fiber more than 15g/1,000 kcal. Diabetes UK also advises that individuals with impaired glucose tolerance should engage in structured programs of lifestyle change with a focus on weight reduction by reducing energy and fat intake as well as increased physical activity. According to the study of diabetes prevention carried out by Colberg, Sigal, Fernhall, Regensteiner, et al. (2010, p.e147), physical activity "is a key element in the prevention and management of type 2 diabetes." Bajpeyi, Tanner, & Slentz (2009) found that exercise stimulates glucose uptake of

muscles. Colberg et al (2003) have documented evidence of the positive effect of the following types of physical exercise on diabetic prevention: aerobic exercise, resistance exercise, and combined exercise. It has been found that exercise decreases cholesterol, improves insulin action and storage in muscle, blood glucose control, as well as fat oxidation (Cohen et al., 2008).

In order to be less prone to develop diabetes mellitus, experts recommend that the following amount of physical activity be maintained on a regular basis: 2.5 hours per week of moderate aerobic activity or 30 minutes a day for 5 days a week. Walking briskly for 2.5 hours a week also contributes to diabetes risk reduction (Jeon, Lokken, Hu, & van Dam, 2007). There are a number of diabetes prevention programs that have been established at the state level in the U.S.

With as many as 86 million in the U.S. having prediabetes, whose risk of developing diabetes mellitus is 4 to 12 times higher than in people with regular glucose tolerance, the National Diabetes Prevention Program (NDPP) attempts to help participants make lifestyle changes as well as reduce their risk of type 2 diabetes development by almost 60% from the baseline.

Research Objectives

The scientific literature documents the implications of controlling modifiable risk factors in reducing the risk of diabetes mellitus. The research question for this study is to assess if there is any effect of the number of sessions on change in weight and physical activity among a sample of adult Nevadans, participating in the NDPP.

Research Questions

Research Question #1: Is percentage weight loss among program participants associated with the number of total sessions attended?

Hypothesis#1:

Ha: There will be a change (drop) in weight of participants attending the healthy behavior sessions in DPP.

Ho: There is no change in the weight of participants attending sessions in DPP.

Expected outcome:

It is expected that weight loss and total number of session attended by the participants are significantly associated with each other.

Research Question # 2: Is increase in physical activity minutes of the program participants associated with the total number of sessions attended?

Hypothesis#1

Ha: Attending more sessions will change (increase) the participants' physical activity minutes per week.

Ho: There will be no change in the physical activity minutes per week of participants attending the sessions.

Expected outcome:

It is expected that there will be a significant association between gain in physical activity minutes and the number of total sessions attended by the participants.

Research Question # 3: Is there any difference in the outcomes across the groups with varied number of sessions attended?

Hypothesis#1

Ha: There is difference in the outcomes (percentage weight loss and increase in physical activity minutes) depending upon their attendance time in the program.

Ho: There will be no difference in the outcomes across the groups with varied attendance of the sessions.

Expected Outcome:

The groups who have attended more sessions, will be more successful in achieving their goals as compared to those who have attended less sessions.

The National Diabetes Prevention Program

The National DPP, which was not in place until 2010, focuses on four major areas: increase of workforce through training, assuring quality through implementation of a recognition program, delivering program through intervention sites, and support of program uptake by health marketing (Albright & Gregg, 2013). In Nevada, NDPP has been recently introduced and structured in a one year curriculum consisting of 16 weekly core sessions on healthy behaviors for an initial six months followed by monthly maintenance sessions for the next 6 months (CDC, About the Program, 2015). The participants were given a goal of 5 – 7% reduction in baseline weight and 150 minutes per week of physical activity (Dinenberg, 2013 & National Diabetes Prevention Program [NDPP], 2015). To effectively measure the success of the program it is vital to assess if the program accomplished the desired goals.

Program Curriculum

The program encompasses two curriculums: First, core curriculum sessions including 16 weekly sessions and second, post curriculum monthly maintenance sessions. Each session was of one hour duration. Every session (except first) starts with reviewing the progress reports for initial 10 minutes, followed by 40- 45 minutes of session activity, and last 5-10 minutes utilized for wrapping the session and assign homework to the participants (Lifestyle Coach Facilitation Guide, p. 10). Self- monitoring is the critical component of this program that will help participants achieving their goals.

The 16 weekly sessions were grouped into three categories, depending upon the discussion topics (Lifestyle Coach Facilitation Guide, p. 25).

Session 1-6 “Getting started”

Session 7&8 “Understanding forces that shape our eating and activity behaviors”.

Session 9-16 focused on the long term change.

The post- core curriculum monthly sessions were aimed at preventing relapse, helping participants to balance their thoughts for long term maintenance and sustaining the behavior change (Lifestyle Coach Facilitation Guide, n.d).

Weight was recorded for every session at the center in a lifestyle coach log (appendix C.1), so the weight measurement chart also served as an attendance sheet (Lifestyle Coach Facilitation Guide, p. 11). The physical activity minutes were self –reported, and the recording started from the 5th session (Lifestyle Coach Facilitation Guide, p. 11). Participants were given a “Food and Activity Tracker” (appendix C.2) and the “How Am I Doing” chart (appendix C.3) for recording their daily food (calories) intake, weight, and physical activity minutes. Participants were also given the “Fat and Calorie Counter” (appendix C.4) for counting their daily intake.

Methodology

Study Design

This study is a longitudinal study, utilizing the secondary data obtained from Dignity Health Saint Rose Dominican Henderson location in Southern Nevada. The Dignity Health is

a not-for-profit organization that aims to foster an environment to improve the overall health of the community and providing high quality of care (Dignity health, n.d.).

Study Sample

Dignity Health Saint Rose Dominican Women's Care & Community Outreach organization introduced this CDC led NDP program to the community through their REACH magazine, health fairs, screening, and speaking engagements. The sample chosen was nonrandom, consists of 66 participants, divided among six groups beginning the same intervention at different start times (Appendix A, figure 1). Groups were formed depending upon availability of the subjects and what days of the week they could attend (morning, afternoon, day of week). The program spanned for one year starting from September 2014 till August, 2015. Group 1 was first to participate in DPP from September 11, 2014, Group 2 started to engage in the intervention from January, 2015. The other groups such as Group 3 and Group 4 had started from February, 2015. The remaining two groups (5&6) started participating in April & July 2015 respectively. The subjects were recruited from employees of Wyndham vacation resort, United Healthcare, and one of the center (Henderson) of the Dignity Health organization, following the selection criteria provided by the CDC. According to the NDPP (2015, p.4) guidelines for recruiting sample:

- The participant should be at least 18 years of age having Body mass index more than or equal to 24 kg/m^2 .
- The participant should have a minimum score of 9 in a survey questionnaire assessing the Diabetes risk. The details of this survey questionnaire can be found on the following web site (<http://www.cdc.gov/diabetes/prevention/prediabetes.htm>).

- Fasting serum glucose level = 100- 125 mg/dl and serum glucose level = 140- 199 mg/dl after consuming 75 grams of glucose
- HgbA1C : 5.7- 6.4 percent

Variables

The dependent variable (DV) includes percentage weight loss and average physical activity minutes (PAM) achieved. Both are continuous variables. However, weight variable was also recoded into a binary dependent variable (1=5% or more baseline weight loss, 0= weight loss < 5% of baseline weight loss).

Data analysis for change in weight and physical activity was performed separately. However, the independent variable used, was the average number of the total sessions attended by the subjects. The statistical models were not adjusted for gender and race due to uniformity of the sample.

For one way ANOVA, we created a categorical variable of the groups depending upon their attendance into the program. The new categories of the groups are:

- Fair attendees (Group 1): The participants who attended fewer than 9 sessions.
- Moderate attendees (Group 2): The participants who attended 9 to 16 sessions.
- Excellent attendees (Group 3): The participants who attended more than 16 sessions.

Requirements for Analysis

According to the Diabetes Prevention Recognition Program (DPRP) standards and operating procedures (2015, p.9, 10 Table 1) requirements 5, 6, 7 & 8 of full recognition standards:

- The subjects attend at least 4 sessions.
- Weight measures are recorded for eighty percent or more of all sessions and physical activity minutes recorded at 60% or more of the sessions attended.

With respect to the requirement of the minimum sessions attended, 6 (Group 6) out of 66 participants did not satisfy the inclusion requirements (as stated above), thus were excluded from the analysis. Therefore, 60 out of 66 participants met the criteria for the inclusion for the weight data analysis. Weight measurements were taken 100% of the time. Therefore, all of remaining 60 subjects were included in the weight analysis. For the physical activity minutes (PAM) analysis, including only the participants having PAM recorded for at least 60% of all the sessions, 51 out of 60 subjects satisfied this requirement, yielding a very small sample size which may provide an inadequately powered statistical model. Therefore, in order to increase the sample size and statistical power, the average of all PAM recordings per subject was utilized. The average percent sessions recorded among all 60 subjects was more than 60%, which justifies also including all subjects in our PAM analysis.

Statistical analysis

To determine the effect of the total number of sessions in the intervention, multiple statistical models were utilized for weight and physical activity separately. IBM SPSS v.23 was used for all analyses. Level of significance and confidence interval was set at $p < 0.05$ and 95% respectively. The sample was predominantly white females, therefore the models

were not adjusted for gender and race. Given the sufficient evidence in literature about the age as an important covariate, we utilized age adjusted linear and logistic regression models.

The models utilized for analysis were, namely:

- Regression models such as multiple linear and logistic regression.
- Association models such as Pearson Correlation
- Difference between the groups model such as one way ANOVA with post-hoc analysis. Groups were re categorized depending upon the level of their session attendance.

Weight analysis: Multiple Logistic Regression analysis was used to determine if the number of intervention sessions was associated with a 5% drop or greater from the baseline weight, with age as a covariate Weight was recoded into a binary dependent variable (1 = 5% or more baseline weight loss, 0= weight loss < 5% of baseline weight loss). This binary variable was the dependent/outcome variable and the average number of total sessions attended was the independent/ predictor variable. A logistic regression analysis was conducted to predict weight loss of at least 5% of the baseline weight among the 60 DPP participants. As the population was majority white females, race and gender were not adjusted for. Multiple linear regression model was utilized to predict how many sessions would be required to achieve a desired weight goal. The average numbers of sessions were used as an independent variable with age as a covariate and % weight loss was a dependent variable. Pearson correlation was performed to ascertain relationship between the number of sessions and % weight loss. All groups had different starting time(s), which restricted our ability to perform repeated measures ANOVA to find out the most effective sessions' series across all of the groups. Therefore, we re-categorized the groups according to their session attendance levels,

which indirectly helped us to compare the different session attendance's outcome. One-way ANOVA was conducted to determine if the percentage weight change was different for groups with different number of session's attendance levels. Participants were re divided into 3 groups depending upon their attendance. Participants who attended more than 16 sessions including maintenance sessions were excellent attendees ($n = 25$), participants who attended 9-16 sessions were named as moderate attendees ($n = 21$), fair attendees ($n = 14$.) are those who have attended fewer than 9 sessions. Also, we did post-hoc adjustments (at 1% significance level) to prevent spurious findings. This model was run separately for both weight and physical activity. Weight % loss and group session attendance levels were used as the dependent and predictor (factor) variables respectively.

Physical activity minutes analysis: Multiple linear regression was utilized for assessing physical activity minutes sustained in the intervention among this population. An initial correlation between the number of sessions in the program and average number of physical activity minutes was performed. One way ANOVA with Tukey's post hoc analysis was performed with average physical activity and group session attendance levels as dependent and factor variables respectively.

Prior to this study, CITI Human Subjects: Social and Behavioral Research Module was completed. Additionally, the data we obtained were already de-identified. This study went through UNLV IRB and received exempt status for secondary data analysis.

Results

Demographics

The given sample consisted of 66 participants, divided among six groups. These groups were formed in the order participants enrolled in the program. All groups had different start time (s) of entering into the program (Appendix A, figure 2). The number of participants among groups varied from a minimum of six to a maximum of fourteen (Appendix A, figure 3). The majority of the participants were females (81.8%) (Appendix A, figure 4). The sample was not racially diverse, since 60 (91%) participants out of 66 subjects were white (Appendix A, figure 5). Additionally the participants ranged in age from 33-78 years with majority of participants in the age group 50-65 years. The mean age of the participants was 60.4 years. Nearly half of the sample population was overweight and class 1 obese. The overall demographic features of the given population can be viewed in Table 1 given below.

In the given sample, 33.3 % (n=22) of the subjects were diagnosed to have prediabetes by blood glucose test, and the risk test was performed on 47% (n=31) participants. Less than one seventh (13.63%) of the sample population were examined by both blood glucose and risk test. Four (4) out of sixty six (66) participants were not verified by any of these tests (Table 1). It is important to note that prediabetes was not determined by the history of gestational diabetes mellitus during prior pregnancy, and may have been self-reported. In a given sample, gestational diabetes mellitus was not reported by any participant.

All participants were overweight with the mean weight of 201lbs. (BMI = 33.63lb. / inch²) in the beginning of the program. As per the program eligibility criteria, the participant should have had BMI at least 24 kg/m². However, 2 out of 66 participants had

BMI less than 24 kg/m², and were not excluded from the study. The number of sessions attended by the participants varied from a minimum of 1 to a maximum 22.5 (range=21.5) (Appendix A, figure 6). The average number of sessions attended among all 66 participants was approximately 13 (median \pm SD=15.5 \pm 6.13). The mean physical activity minutes per week was 158.2 minutes at baseline. All baseline and final average weight loss and physical activity minutes measurements showed in Table 2.

Table 1: Study Population Demographics

Parameters	Median \pm SD	(Min, Max)	N=66	Percentage (%)
Age (In years)	63.5 \pm 12.13	(33,78)		
Gender				
Male			12	18.2
Female			54	81.8
Race				
White			60	91.0
Non White			6	9.0
BMI				
Normal: less than 25			5	7.6
Overweight: ≥ 25 - < 30			17	25.8
Obesity Class I: ≥ 30 - < 35			17	25.8
Obesity Class II: ≥ 35 - < 40			12	18.1
Obesity Class III: ≥ 40			15	22.7
Pre diabetes determination				
Blood Glucose Test			20	
GDM			ND	
Risk Test			31	47
Blood Glucose			22	33.3
Both (Glucose test & Risk Test)			9	13.63
No Test			4	6.1

Abbreviations: GDM, Gestational Diabetes Mellitus, ND – Not Determined (Prediabetes was not determined by the history of GDM during previous pregnancy, may be self-reported).

Table 2: Average weight loss and physical activity measurements pre and post intervention.

Variable	Number	Baseline measurement (average)	Final measurement (average)	Change
Average number of sessions attended	13			
Mean weight (lbs.)		235.4	227.87	(-) 7.53
BMI (lb./inch ²)		35.12	33.24	(-) 1.88
PA (In minutes)		158.2	175.72	(+) 17.52

Abbreviations: PAM, Physical activity minutes, Average number of session- average of weekly core sessions and monthly maintenance sessions, BMI, Body mass index

Baseline Measurement: Measurement taken at First session, Final Measurement: Last session measurement.

(-) Indicates Drop

(+) Indicates Increase

Weight Analysis

The crude odds ratio indicated that for every increase in one intervention session, the odds of dropping weight at 5% or greater from baseline increased significantly by 24% (Odds Ratio (OR) = 1.24 (95% confidence interval (CI): 1.093-1.418; $p < .05$) (Appendix D.1). The odds of achieving the desired weight loss goal was 24% more likely for each additional session attended in the intervention (Table 3). The odds ratio (after age adjustment) dropped to 20% ($p < .05$), presenting the total session as a stronger and more significant variable than age ($p > .05$). Additionally, in logistic regression with only age as a predictor variable, it was statistically significant ($p < .05$), indicating an independent association between age and weight loss (Appendix D. 9).

Table 3: Multiple Logistic Regression Model

Variable	Exp. (b)	Confidence Interval	P Value
Total Sessions**	1.245	(1.093 - 1.418)	.001
Total Session*	1.204	(1.054 - 1.376)	.006
Age	1.064	(0.986 - 1.149)	.112

Total Sessions** = crude estimate

Total Session* = adjusted for age

The results of the Pearson's correlation indicated that there was a significant direct correlation ($r = 0.451$, $p < .05$) between the average number of sessions attended and percentage weight loss (Appendix D.2).

The results from the linear regression indicated that with every unit increase in one intervention session, there was a significant ($p < .05$) weight loss by 0.33 percent (Table 4). And, the intervention alone accounted for 20.3% of the variability in the percentage weight loss. In the age adjusted multiple regression model, the total session variable overrides the effect of age on the outcome, presented age as an insignificant predictor ($p = .242$, table 4). However, age alone was shown to be independently and strongly associated with the outcome (Appendix D.10).

Table 4: Multiple Linear Regression

Predictor	R^2	B	P Value
Total Sessions*	0.203	0.33	0.000
Age	0.223	0.052	0.24
Total Sessions**		0.286	0.004

* $R^2 \times 100 = 20.3\%$ variation in outcome, Total Sessions* = Crude estimate

** $R^2 \times 100 = 22.3\%$ variation in outcome, Total Session** = Age adjusted

Table 5: One way ANOVA for groups with different levels of session attendance

			95 % confidence interval for mean	
Group	N	Mean \pm S.D	Lower Bound	Upper Bound
1	14	1.50 \pm 2.32	0.16	2.85
2	21	4.50 \pm 3.13	3.06	5.91
3	25	6.29 \pm 4.38	4.48	8.10

Groups were divided depending upon the sessions attended, group 1 (session attendance < 9), group 2 (session attendance 9-16), group 3 (session attendance > 16).

Data were presented as mean \pm standard deviation. The average % weight loss increased from the fair attenders group 1 ($n = 14$, 1.52 ± 2.32), to moderate attenders group 2 ($n = 21$, 4.49 ± 3.13), to excellent attenders group 3 ($n = 25$, 6.29 ± 4.38). Groups were divided depending upon the sessions attended, group 1 (session attendance < 9), group 2 (session attendance 9-16), group 3 (session attendance >16). The ANOVA results also indicated that the % weight loss was statistically significantly different for different levels of session attendance, $F(2, 57) = 8.053$, $p < .01$ (Appendix D.7). Tukey post hoc analysis revealed that the mean increase from fair to excellent attenders (4.79 , 99% CI [1.16 , 8.41]) was statistically significant ($p = .001$), but no other group differences were statistically significant.

Physical activity minutes analysis

The regression model tested whether total average sessions attended predicts (improves) average physical activity minutes sustained (Figure 1). The results indicated that the intervention sessions account for 10.7% ($p < .0001$) of the variation in physical activity minutes (Appendix D.5). In other words, 89.3 percent of variation was explained by factors other than average number of sessions. A p value less than 0.05 is the significance level for determining whether the number of total sessions significantly predicts physical activity minutes. The results of the simple linear regression indicated that for every increase in session, there will be an increase in physical activity minutes achieved of 8.3 minutes ($p < .05$, Table 7) (Appendix D.6). However, the results of the multiple regression (with age as a covariate), indicated the session as a stronger predictor variable as compared to age ($p = .081$, Table 6). This p value, which is close enough to be considered as a significant, suggested that more sample size will be required to validate the results.

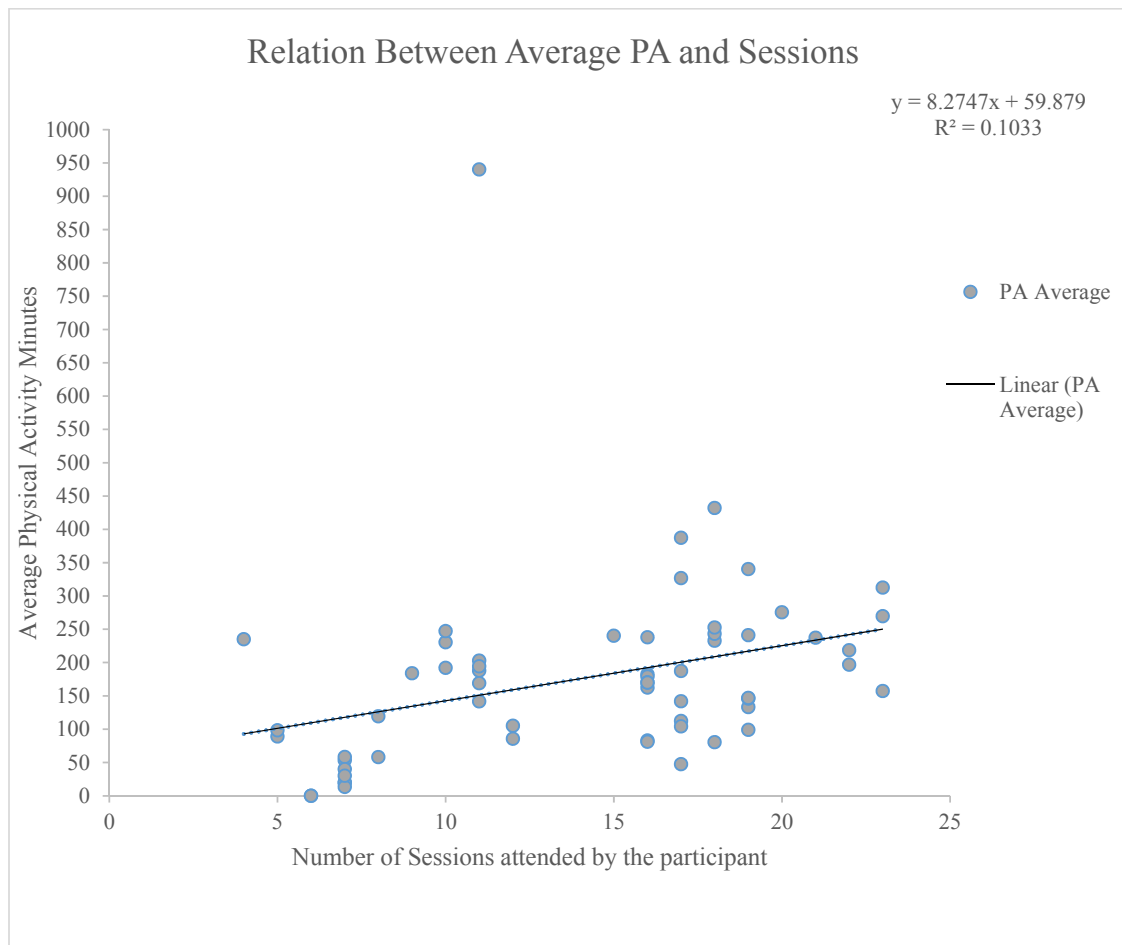


Figure 1 - Linear relationship between average PA and sessions

The scatter plot showed a positive linear relationship between the average physical activity minutes and total number of sessions attended by the participants. The total number of sessions referred to weekly core sessions as well as monthly maintenance sessions. Subject with a value of higher than 16 sessions corresponded to the participants of group 1, who attended 16 weekly core sessions and additional monthly maintenance sessions.

Table 6: Multiple Linear Regression			
Predictor	R ²	B	P Value
Total Sessions*	0.103	8.275	0.012
Age	0.135	2.345	0.157
Total Sessions**		6.190	0.081

R²×100 = 10.3 % variation in outcome, Total Sessions = Crude estimate
R²×100 = 13.5 % variation in outcome, Total Session = Age adjusted

The results of the Pearson's correlation indicated that there was a significant direct correlation ($r = 0.321$, $p \text{ value} < .05$) between the total number of sessions and physical activity minutes (Appendix D.4). As mentioned earlier, gender and race were not used as covariates because the population was comprised predominantly of white females. In age adjusted multiple regression model, the number of session predictor variable was stronger than the age ($p = 0.081$, $p = 0.157$) and requires more sample to validate the results. However, age was independently and strongly associated with the outcome, when used separately (Appendix D.11).

Table 7: One way ANOVA for groups with different levels of session attendance				
			95 % confidence interval for mean	
Group	N	Mean ± S.D	Lower Bound	Upper Bound
1	14	59.61 ± 62.25	23.672	95.55
2	21	208.89 ± 174.8	172.20	253.56
3	25	212.88 ± 98.54	139.80	211.64

Groups were divided depending upon the sessions attended, group 1 (session attendance < 9), group 2 (session attendance 9-16), group 3 (session attendance >16).

Data were presented as mean ± standard deviation. The average % weight loss increased from the fair attenders group 1 ($n = 14$, 59.61 ± 62.25), to moderate attenders group 2 ($n = 21$, 208.89 ± 174.8), to excellent attenders group 3 ($n = 25$, 212.88 ± 98.54). The ANOVA results also indicated that the average physical activity minutes were statistically significantly different for different levels of session attendance groups, $F(2, 57) = 7.849$, $p <$

.01 (Appendix D.8). Tukey post hoc analysis revealed that the mean increase of physical activity minutes increased from fair (Group 1) to excellent attenders (Group 3) (153.3, 99% CI [73.14, 233.4) was statistically significant ($p = .000$), but no other group differences were statistically significant.

Discussion

This study was conducted to determine: 1) if total sessions attended were significantly and directly associated with change (drop) in weight, 2) if total sessions were significantly and directly associated with increase in physical activity minutes, and 3) if there were differences in the outcomes (weight loss and gain in PAM) across the groups with varied number of sessions attended. We used multiple logistic, multiple linear regression, and one way ANOVA to test our hypotheses related to three research questions, stated above. All of the three null hypotheses were rejected and indicated that the number of sessions were directly and significantly associated with the weight loss and gain in physical activity minutes. Additionally, there were significant differences of the outcomes across the groups with different level of session attendance. Demographic variables such as gender and race were not adjusted in the models, since the sample was predominantly white females. Initially, when separate regression models were used for total session and age as independent variables, the results were significant, indicating the independent association of these two variables with the outcome. However, after having them entered in the same model, age was no longer significant, indicating the effect of the intervention on the outcome was stronger than the effect of age.

The mechanism of advancing age in increasing the risk of Type 2 diabetes mellitus has already been well established in the scientific literature. Advancing age has been

associated with beta cells malfunctioning, decreasing insulin sensitivity and increasing glucose intolerance among elderly (Suastika, 2012). Given the interactions between age and its associated outcomes, it becomes even more difficult to lose weight, gain physical activity, and sustain behavior change, with the age progression (Lee et al, 2010). Therefore, our finding that the age is independently and strongly associated with the study outcomes, is critical and consistent with the findings reported in the past years.

Several clinical trials, showed that diabetes risk can effectively be reduced to 58% by implementing lifestyle change interventions (Marrero, 2009). Three major clinical trials such as Da Quing Study, Finish Diabetes Prevention Study, and Diabetes Prevention Study were conducted in the past to ascertain the effectiveness of lifestyle change intervention (Marrero, 2009). These study results indicated that with moderate loss of weight (5-7%) and increase physical activity (150 minutes/ week) can significantly reduce the risk of diabetes. Most noticeably, it was also concluded that the sessions in Diabetes Prevention Study were effective, irrespective of age and race (Marrero, 2009).

The scientific literature also highlighted the importance of behavior change intervention especially group based sessions, in decreasing the weight and gaining the physical activity. According to Gillison et al (2015), group based intervention were very important in promoting healthy behaviors. These interventions helped utilizing motivational social support and self-regulation for sustaining the behavior change (Gillison et al, 2015). According to results obtained during process evaluation of a lifestyle change intervention, conducted in England, there was a significant reduction in the mean weight by 4.07 lbs. (from baseline) over the period of 12 months (post intervention) (Gillison et al, 2015). Our study results also confirmed the association between the program sessions and weight loss. The average weight loss achieved was nearly 8 lbs. at the end of the intervention. The weight loss results provided a promising insight pertaining to the effectiveness of the sessions. Moreover,

the intervention sessions also contributed to the gain in the physical activity among the participants. Although, physical activity recordings started from the fifth session, but, most of the participants were physically active from the first session, hence were called early adopters. These participants were successful in meeting their physical activity goals of 150 minutes/ week.

One more study – Life in balance (LIB) project, was adapted from the Diabetes Prevention Study (Benyshek et al, 2013). The study was performed in urban American Indian/ Alaskan Native communities (Benyshek et al, 2013). The core curriculum was similar as that of DPP clinical trial. The results of this study indicated that there was a significant drop in the average weight by 5.79% from the baseline among those who attended complete intervention session series (Benyshek et al, 2013). Similarly, our study also indicated that the participants who were excellent attendees, lost maximum amount of weight (mean weight loss = 6.29 lbs.) from baseline.

According to one meta-analysis done on 28 U.S based studies, overall the average weight change during the course of 12 months lifestyle intervention was nearly 4% (from the baseline) , which is comparable to our study's overall weight change (3.2%) (Dinenberg, 2013).

Strengths and Limitations

First, the predictive models utilized in the study will help in setting the weight and activity goals for the future subjects and also in determining the efficacy of the program. Knowing the program's outcome and efficacy will help in future planning and health resources allocation. Second, the subjects were recruited based upon the biochemical indicators (blood glucose estimation) as well as the prediabetes risk assessment score. Using

both criteria for diagnosing prediabetes, will guarantee the broader coverage of the people, predisposed to having type 2 diabetes mellitus. Third, the major strength of the study lies in its ability to perform comparability tests in reference to the recordings taken at the first or previous sessions. Fourth, this pilot study will aid determining the minimal clinically significant difference across the groups of participants attending varied number of sessions, which would then be utilized for power analysis for prospective large trials. Lastly, the weight recordings were recorded at the intervention sites instead of being self-reported, which would help increase the accuracy of the results.

Among limitations of the study, first, is that the study lacks generalizability owing to its small sample, which is not representative of the entire population. So, we findings cannot be extrapolated to other populations. Furthermore, studies done on the small samples may also give overestimated odds ratio, which may question the validity of the results, yielding underpowered model. In addition, the sample was not diverse by gender, race, ethnicity, which restricted our ability to adjust for these variables. It is important to note that age, although a univariate associate of the outcome, was no longer significant in the presence of other stronger variable (number of sessions). The number of session variable remains significant or approaches significance in every model indicating its powerful attribute in explaining the outcomes.

Second, the data did not contain the participants' sociodemographic characteristics such as dietary habits, smoking status, alcohol consumption history, education status, income, occupation, insurance/ payer information, comorbidities, and any drug history, that might have contributed to the outcomes. Also, information pertaining to past weight loss practices (dieting or exercise) being used by the participants, was lacking. Therefore, it may not be stated that the positive outcomes were solely due to intervention. Possibly, other unrecorded

factors might have contributed to the outcome. Third, the most important weakness was that the number of sessions across the subjects were not uniform due to groups' different start up times to enter into the program. Some of the groups could not even complete their sessions, because of joining late in the intervention. This huge variability in times and sessions did not allow us to find the most effective session for the desired outcome. Fourth, it should be noted that fewer measurements were taken (started at session 5) for physical activity as compared to weight loss measurements, which may potentially yield underestimated results for the physical activity analysis. Fifth, the physical activity was self – reported, which lacks validity and can introduce bias in the study. Standardized measurement of the physical activity minutes was lacking. Sixth, loss to follow up (attrition rate) was 22%, which was an additional source of bias in the study. Given the underpowered model, there will be tendency of the bias to shift the study results towards the null. Seventh, absence of control group in the study may threaten the validity of the results.

Eighth, the risk assessment survey (Appendix C.4) was not reliability or validity tested statistically for ascertaining the population at risk of developing Type 2 diabetes mellitus. The risk assessment should not be entirely based on the prediabetes survey, since it may be possible for someone having a risk score < 9, still yielding a positive biochemical test. Therefore, a reliability test for the prediabetes survey should have been conducted to prevent false negative results and increase sensitivity. In addition, questions related to the smoking, waist circumference, fruits and vegetable consumption, history of taking anti hypertensives were lacking in the risk assessment survey.

Avenues for Prospective Research

The current study may create the foundation for prospective studies to determine if the suggested intervention has been successful in reducing the risk of type 2 diabetes mellitus. It will be intriguing to perform outcome evaluation in subsequent studies with a larger and more heterogeneous sample.

Public Health and Clinical Implications

Following this intervention with some kind of outreach activities to determine the relapse of the unhealthy behavior (physical inactivity and improper diet) and also by incorporating maintenance strategies for an extended period of time to make the sustained change in behavior will be critically important. The strategies to maintain the healthy dietary habits and restoring physical activity should be incorporated at the earlier stages of life and be a part of our daily routine. For instance, fitness courses should be offered at school level to help children to adopt active lifestyles. Education programs targeting parents is required to reinforce the active behavior at home. Parents should learn how to engage their children in active outdoor activities. Altering behaviors early in life is relatively easy and more sustainable as compared to behaviors introduced later.

Other recommendations include educating physicians to correctly diagnose prediabetes and providing weight counseling to the patients at risk of developing Type 2 diabetes mellitus. Physicians should be given enough knowledge about the ways of modifying behaviors of the patients. Integration of individual medical practice with community based interventions will help in overcoming the barriers currently encountered in diagnosing prediabetes. Also, the program should be adequately marketed at the provider level, so that appropriate referrals can be made. Policymakers should alter the built

environment by providing more bike lanes and pedestrian pathways. These will certainly help the public to have sustained change in behavior. Collaboration with insurance companies to help deliver such interventions at minimal cost would be an essential step in making the intervention widely distributed across the populations with different socioeconomic statuses.

Conclusion

The results indicate that the Diabetes Prevention Program is successful in achieving both weight loss and physical activity goals among this population. The average weight loss of all participants was 3.2% of the baseline weight which fairly aligns with the desired goal of 5% weight loss from baseline. Similarly, the program has been helpful in increasing physical activity minutes sustained among the subjects. The results indicate an average increase of 17.52 minutes of physical activity per week as compared to the average baseline measurement taken at the fifth session. The existing results for this sample yields promising insight regarding the success of the program. Follow up analyses can be performed upon increasing the size and variability of the sample.

Appendix A

Graphical representation

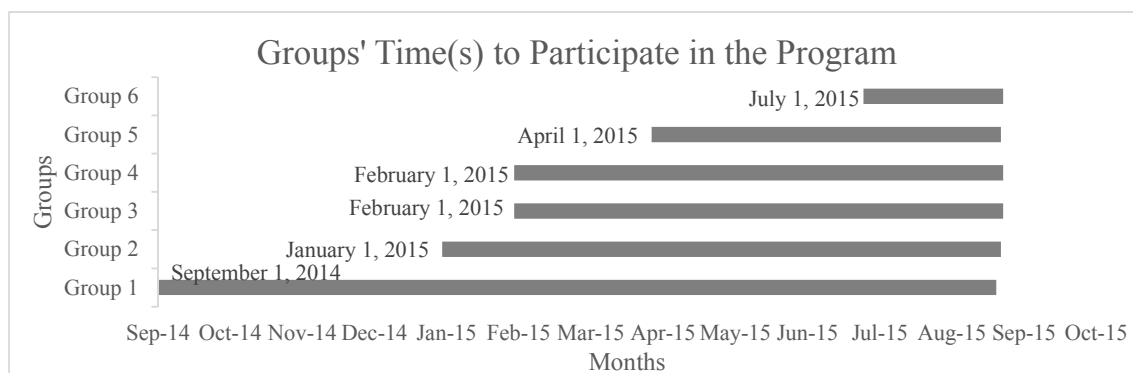


Figure 2 - Bar graph different startup times(s) of the groups

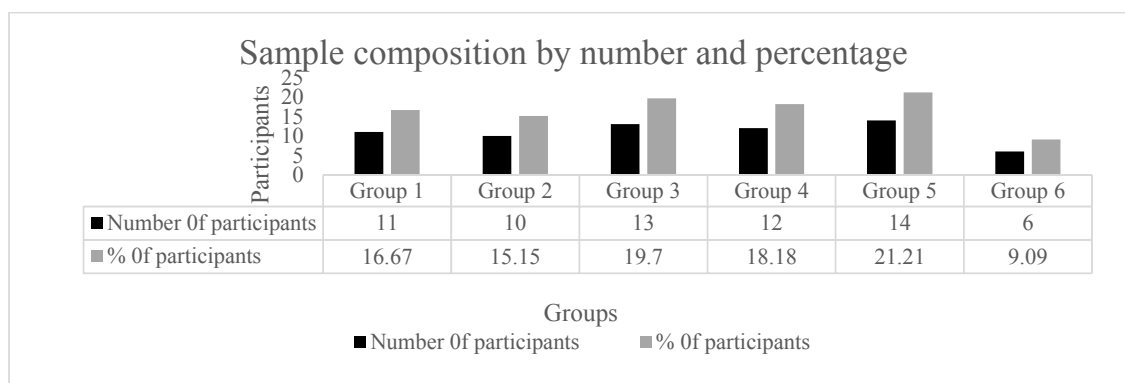


Figure 3 - Bar graph number and percentage composition of a sample

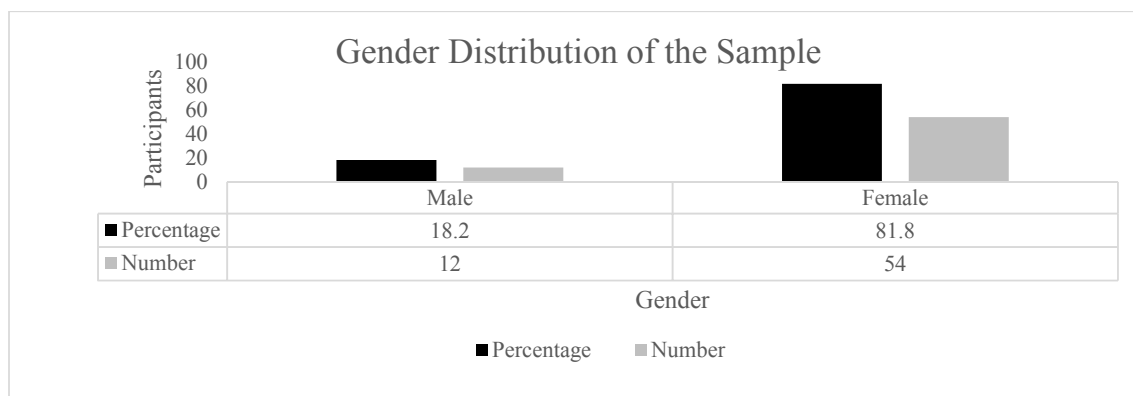


Figure 4 - Bar graph gender composition of the sample

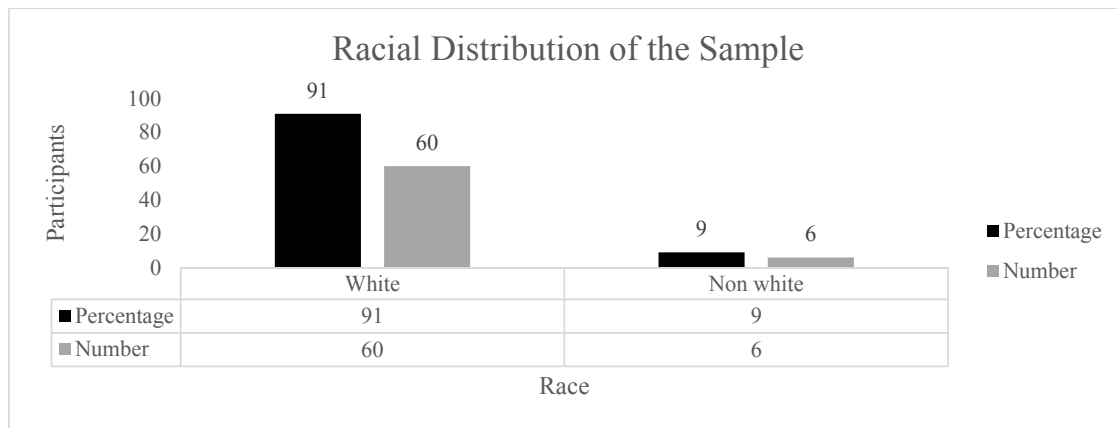


Figure 5 - Bar graph racial distribution of the sample

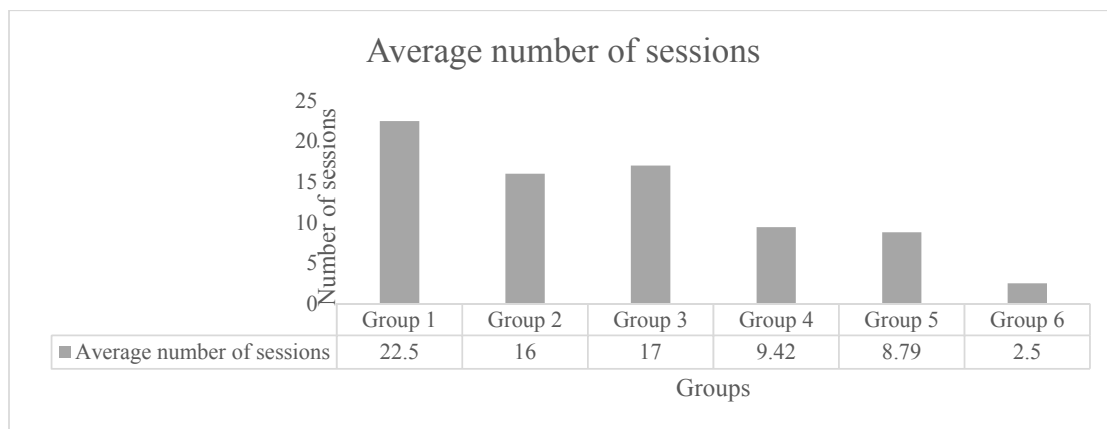


Figure 6 - Bar graph average number of sessions among groups

Appendix B

List of Acronyms

ANOVA	Analysis of Variance
BMI	Body Mass Index
CDC	Centers for Disease Control
CI	Confidence Interval
CITI	Collaborative Institutional Training Initiative
DM	Diabetes Mellitus
DPPRG	Diabetes Prevention Program Research Group
DPRP	Diabetes Prevention Recognition Program
DV	Dependent Variable
GDM	Gestational Diabetes Mellitus
IRB	Institutional Review Board
IV	Independent Variable
NDPP	National Diabetes Prevention Program
OR	Odds Ratio
PAM	Physical Activity Minutes
SPSS	Statistical Package for the Social Sciences
UNLV	University of Nevada Las Vegas
WHO	World Health Organization

Program Materials

[illegible][illegible]

3. How Am I Doing Chart

[illegible]

4. Fat and Calorie Counter

ITEM	SERVING	FAT (g)	CALORIES	ITEM	SERVING	FAT (g)	CALORIES
Baked Beans:				homemade, with stew meat,			
vegetarian baked beans	1/2 cup	1	127	trimmed, no fat added	1 cup	7	192
pork and beans (Campbell's®)	1/2 cup	2	140	homemade, with stew meat,			
Baklava, 2" square	1 pc	27	381	trimmed, fat added	1 cup	11	228
Bamboo shoots, canned	1/2 cup	0	12	homemade, with stew meat,			
Banana, fresh, 8" long	1 each	0	96	untrimmed, fat added	1 cup	16	269
Banana pudding,				canned	1 cup	14	237
With vanilla wafers	1/2 cup	4	152	Beef Stroganoff (no noodles),			
Barbecue sauce	1 Tbsp	0	12	homemade:			
Barley	1/2 cup	0	96	with round steak, trimmed,			
BBQ sandwich, on a bun:				nonfat sour cream, no fat			
chicken	1 med	6	245	added	1 cup	5	
pork	1 med	10	341	with beef cubes, trimmed,			
beef	1 med	18	396	nonfat sour cream, no fat			
Beans and peas, dried (navy, lima,				added	1 cup	14	310
red, pinto, kidney or black				with beef cubes, trimmed,			
beans, split peas, lentils, black				low fat sour cream, fat added	1 cup	22	378
eye peas, pigeon peas):				with beef cubes, untrimmed			
no fat added	1/2 cup	1	129	regular sour cream, fat added	1 cup	37	485
cooked with bacon,				Beer (1 can = 12 fl oz):			
ham or sausage	1/2 cup	2	144	low calorie	1 can	0	101
Beans, green, or Italian:				regular, malt, or no alcohol	1 can	0	148
no fat added	1/2 cup	0	19	Beets	1/2 cup	0	37
cooked with bacon, ham				Biscochitos (cookie), 1 1/2" diam	1 pc	3	58
or sausage	1/2 cup	2	34	Biscuit, from refrigerated			
Beans, mung	1/2 cup	0	139	dough:			
Beef, canned	1/2 cup	10	166	buttermilk (Pillsbury®)	1 each	1	50
Beef jerky:				buttermilk, flaky			
strip, 8 1/2" x 1" x 1/8"	1 pc	3	67	(Hungry Jack®)	1 each	4	90
cut pieces	1/2 cup	8	204	Grands! (Pillsbury®)	1 each	8	190
Beef stew, gravy-based,				Biscuit, from mix, small, 2" diam	1 each	7	125
with vegetables:				Biscuit, mix only:			
homemade, with round steak,				Bisquick® Light	1/3 cup	2	150
trimmed, no fat added	1 cup	3	161	Bisquick®	1/3 cup	6	170
				Blackberries, fresh	1/2 cup	0	37

5. Prediabetes Risk Assessment Survey

Take the Test - Know Your Score!

Answer these seven simple questions. For each "Yes" answer, add the number of points listed. All "No" answers are 0 points.

	<u>Yes</u>	<u>No</u>
Are you a woman who has had a baby weighing more than 9 pounds at birth?	1	0
Do you have a sister or brother with diabetes?	1	0
Do you have a parent with diabetes?	1	0
Is your body mass index (BMI) 27 or greater?	5	0
Are you younger than 65 years of age and get little or no exercise in a typical day?	5	0
Are you between 45 and 64 years of age?	5	0
Are you 65 years of age or older?	9	0
Total points for all "yes" responses:		
Above 9 Points at high risk		

Appendix D

SPSS Output Tables

1. Variables in the equation table

					95% C.I for EXP (B)	
	B	Wald	Sig.	Exp. (B)	Lower	Upper
No of Sessions	.219	10.901	.001	1.245	1.093	1.418

2. Association model for weight

		Weight Change (%)	No. of Sessions
Pearson Correlation	Weight Change (%)	(1.093-1.418)	0.001
	No. of Sessions	.451	1.000
Sig. (1-tailed)	Weight Change (%)	.	.000
	No. of Sessions	.000	.
N	Weight Change (%)	60	60
	No. of Sessions	60	60

3. Regression Model

Model	Unstandardized Coefficients	Standardized Coefficients		95.0% Confidence Interval for B		
	B	Beta	t	Sig.	Lower Bound	Upper Bound
Constant	-.108		-.083	.934	-2.700	2.484
No. of Sessions	.332	.451	3.849	.000	.160	.505

Dependent variable: Weight Change (%)

4. Association model for physical activity

		PA Average	No. of Sessions
PA Average	Pearson Correlation	1	.321*
	Sig. (2-tailed)		.012
	N		60
No. of Sessions	Pearson Correlation	.321*	1

	Sig. (2-tailed)	.012	
	N	60	60

*. Correlation is significant at the 0.05 level (2-tailed).

5. Regression Statistics.

Model	R Square	Adjusted R Square
1	.107	.092

6. Regression model for physical activity

Model	Unstandardized Coefficients	Standardized Coefficients	t	95.0% Confidence Interval for B		
	B	Beta		Sig.	Lower Bound	Upper Bound
Constant	59.879		1.248	.217	-36.154	155.912
No. of Sessions	8.275	.321	2.585	.012	1.868	14.681

7. ANOVA for % Weight

	Sum of Squares	df	Mean Square	F	Adjusted R Square
Between Groups	206.103	2	103.052	8.053	.001
Within Groups	729.380	57	12.796		
Total	935.483	59			

8. ANOVA for Physical Activity

	Sum of Squares	df	Mean Square	F	Adjusted R Square
Between Groups	246365.222	2	123182.611	7.849	.001
Within Groups	894592.535	57	15694.606		
Total	1140957.757	59			

9. Logistic Regression with only age as a predictor for Weight.

Variable	Exp. (b)	Confidence Interval	P Value
Age	1.087	(1.017 - 1.162)	.014

Age = crude estimate

10. Linear Regression with age as the predictor for Weight.

Predictor	R^2	B	P Value
Age	0.098	0.108*	0.015

$R^2 \times 100 = 9.8\%$ variation in outcome

0.108* = unit of percentage weight loss

11. Simple Linear Regression with age as the predictor for Physical Activity.

Predictor	R^2	B	P Value
Age	0.087	3.552*	0.022

$R^2 \times 100 = 8.7\%$ variation in outcome

3.552* = unit of increase

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