THE LONG-TERM EFFICACY OF A BEHAVIORAL BASED DIABETES PREVENTION PROGRAM FOR HIGH RISK HISPANIC YOUTH

A thesis submitted to the University of Arizona College of Medicine – Phoenix
in partial fulfillment of the requirements for the Degree of Doctor of Medicine

Mia Wright
Class of 2019

Mentor: Maurice Lee MD, MPH, FAAFP

Acknowledgements

Dr. Maurice Lee

Paul Kang

Cristal Cathey

Abstract

Background/Significance: Little is known about the long term efficacy of diabetes prevention programs that target high risk youth. The purpose of this study was to determine the long-term efficacy of a behavioral & medical based diabetes prevention program targeted at high risk youth. At the St. Vincent de Paul Medical & Dental Clinic (SVdP), the Every Little Step Counts (ELSC) diabetes prevention program has recruited high risk Hispanic youth to participate in 12 bi-weekly classes since 2005. No long term follow-up has been collected since the start of the program.

Research Question: In adolescents younger than 18 (P), what is the long term efficacy (O) of St. Vincent De Paul's behavioral and medical based integrated diabetes prevention program (I) compared to other behavioral based programs or no intervention at all(C)?

Methods: Twenty-one adolescents who completed ELSC were recruited as the intervention group. 9 youth in the community who did not complete the program were recruited as the control group. The HbA1c, BMI% and BP were measured as well as a health behavior questionnaire. BMI% and BP% are percentiles based on the child's age and height using charts established by the CDC (13).

Results: There was no significant difference in A1c% ($p=0.87$), Systolic BP and BP% ($p=0.21$ and $p=0.29$), BMI% ($p=0.11$) and health behaviors ($p>0.05$) between adolescents who completed the program (intervention) versus those who did not (control). Diastolic BP, diastolic BP% ($p=0.02$ and $p=0.04$) & BMI ($p=0.02$) were lower in the intervention group compared with the control. The intervention group demonstrated a decrease in A1c% ($p=0.001$) but an increase in BMI% at the follow-up compared with their baseline.

Conclusions: This data suggests that there is no overall benefit to decreasing the risk of diabetes. There was improvement in some markers of metabolic syndrome in at risk adolescents and decline in others. The program is now planning on incorporating overall life skills and goals into annual reunions instead of focusing primarily on weight as a way to continue the benefits gained during the program . Future follow up will be needed to determine if the behavioral based programs can be effective in decreasing the incidence of diabetes in a population already at high risk.

Table of Contents

Introduction, Significance and Rationale 1

Research Question 4

Materials and Methods 5

Results 10

Discussion 18

Conclusions 21

References 22

List of Figures and Tables

Figure 1: Health Behavior Survey 8

Table 1: Demographic Characteristics of the Participants 11

Figure 2: Survey Screen Time and Physical Activity........ 12

Figure 3: Survey Eating Behaviors 13

Figure 4: Hgb A1c overtime & intervention vs. control 15

Figure 5: BMI% overtime & intervention vs. control 16

Figure 6: Diastolic BP% intervention vs. control 17

Introduction, Significance, and Rationale

Obesity and diabetes (Theme)

Research has demonstrated a steady increase in the rates of obesity and the subsequent disease burden that comes with it. The United States has the highest rates of overweight and obesity incidences of all high-income countries with a third of the population being obese (11). This rate is projected to rise to 50 percent by 2030 (11). These rates are alarming considering the comorbidities associated with obesity including diabetes mellitus, hypertension, hyperlipidemia, cardiovascular disease, depression, respiratory disease and many others. In the Nurses' Health Study, middle-aged women with a body mass index (BMI) of 35 or higher compared to women with BMIs lower than 22 had a 93 times higher risk of developing type 2 diabetes (4). Between 1994 and 2010 the percentage of adults with diagnosed diabetes who were overweight or obese increased from 69.7% to 84.7% (1). With the increasing rates of obesity worldwide a subsequent rise in type 2 diabetes prevalence has also been observed. The link between diabetes and obesity is significant and threatens the individual lives of patients and the healthcare system.

Obesity and rising health care costs

Treating obesity and obesity related conditions, such as diabetes, is an important but costly healthcare endeavor. In 2005 the US obesity-related health care spending was estimated at $190 billion (3). This finding implicated that previous literature had underestimated the financial burden of obesity therefore affecting government intervention to combat the epidemic (3). If the obesity epidemic continues to escalate the healthcare costs related to obesity could rise by $66 billion a year by 2030 (11). On an individual level, costs per person for obesity and obesity related conditions is significantly higher than normal weight adults (11). Spending for obese individuals is 150% higher than for non-obese individuals (3). These lifetime costs raise alarming questions about the long-term effects of recent obesity trends on the healthcare system.

Childhood obesity and diabetes

The increase in childhood obesity and subsequent increase in type 2 diabetes amongst adolescents has also been on the rise. Since 1990 there has been a 60 percent increase in the number of overweight or obese preschool children with 43 million being reported in 2010 (6). These children will require chronic management and undoubtedly health care costs will continue to increase because of the life-time care these patients will need. The link between increasing rates of obesity and cases of type 2 diabetes in adolescents has also been documented in many studies. The prevalence of type 2 diabetes in the United States increased by 30.5% in youth 10 to 19 years old between 2001 and 2009 (5). Of the youth with type 2 diabetes, 79.4% were obese and 10.4% were overweight (9). As this trend continues the comorbidities associated with adolescent obesity and type 2 diabetes including the financial cost will also rise.

Adolescent Obesity and diabetes prevention programs: What's already been done?

There have been many approaches to preventing obesity and diabetes. Substantial evidence exists among interventions targeting adults. According to the Diabetes Prevention Program Research Group, a ten-year follow-up of the Diabetes Prevention Program Outcomes Study demonstrated the cumulative incidence of diabetes remained lowest in the lifestyle intervention group, compared to metformin or nothing(12). Unfortunately there is still limited evidence for diabetes prevention in youth. Interventions have traditionally focused on the individual with limited evidence for their efficacy. Adolescent obesity prevention programs oriented around behavior change have shown limited long-term effects (2). Current interventions lead to short-term improvements in outcomes related to obesity (7). Schools have been found to be an important setting for interventions to positively impact outcomes and physical activity was a critical component of interventions targeting obesity prevention (7). According to a comparative effectiveness review and meta-analysis, school-based interventions for childhood obesity prevention have less evidence for effectiveness than other forms of interventions (10). Programs with the most evidence for effectiveness included physical activity in a school-based setting with a family, home and/or community component (10). In adolescents experiencing severe obesity, bariatric surgery is increasingly considered as a treatment option though there are few studies showing the efficacy and safety in this age group (8). Significant improvements have been demonstrated in weight, cardiometabolic health and weight-related quality of life three years after receiving bariatric surgery, and 95% of participants had remission of type 2 diabetes (8). .

Despite this evidence many gaps in knowledge still exist in the area of adolescent obesity and diabetes prevention. The NEJM bariatric study supports the idea that bariatric surgery might be a viable option for some youth but it is invasive and has not been compared to other groups who have received behavioral health interventions. In addition, many programs have failed to integrate chronic disease prevention into their obesity prevention programs (7). There is a strong association between obesity and chronic disease in youth; thus, obesity prevention is equivalent to type 2 diabetes prevention. Other gaps in knowledge include limited information on interventions in home and community settings as well as a lack of population-based interventions (7).

Research Question

In adolescents younger than 18 (P), what is the long-term efficacy (O) of St. Vincent De Paul's behavioral and medical based integrated diabetes prevention program (I) compared to other behavioral based programs or no intervention at all (C)? This was a retrospective study of adolescents <18 who have completed St. Vincent De Paul's Every Step Counts diabetes prevention program. At-risk adolescents who have completed the program were screened for the presence or absence of diabetes after having completed the program. Quantitative (A1c, BMI, BP) and qualitative (health behaviors) factors were assessed for each group and the results were compared to a similar group of adolescents who did not complete the program. We hypothesized that adolescents who completed the Every Little Step Counts program will have less incidence of diabetes than a group of adolescents who have not completed the same program. We also hypothesize that the adolescents involved in SVdP's Every Step Counts program will have lower BMI's, A1c levels and BP's than adolescents from similar populations who did not complete the program.

Materials and Methods

The aim of this study is to determine the long-term efficacy of St. Vincent de Paul's Every Little Step Counts program at preventing diabetes in high risk youth <18 years old.

St. Vincent De Paul's Every Little Step Counts Program

St. Vincent de Paul's Every Little Step Counts program recruits high risk youth to enter their diabetes prevention program from throughout the community. They can be referred by their physician, recruited from health fairs, social media, or an ad in a Hispanic magazine that is popular in the community. The children may be insured or uninsured but they must be Hispanic and bilingual. When recruited, they are called and screened to see if eligible for the program. The inclusion for this program include youth <16 years old that are in the >90th% BMI percentile and have at least two other associated risk factors: Family history, Hispanic, abnormal labs, pre-diabetes. Exclusion criteria for the program includes a diagnosis of diabetes or previous treatment for diabetes. After they are enrolled, the children get designated to a specific program depending on their age. Parents come in for labs and biometric measurements as well. The program consists of twelve bi-weekly classes that are two hours long. There is of one-hour physical activity and one hour split between wellness and nutrition. Wellness classes include topics such as self-esteem, empowerment, social skills, and emotional coping. Class topics vary from healthy plates, parent roles, physical activity, setting up plans for eating, going over the meaning of their labs, and discussing how diabetes and these classes impacts their family's health. Family involvement is a requirement. At the end of the program, biometrics and lab data are drawn on the family and they are connected to continuing care.

Subjects

Adolescents who completed or were recruited but did not complete St. Vincent de Paul's Every Little Step Counts diabetes prevention program were recruited to participate in this study. Subjects were identified through a database review of SVdPs ELSC program data. All adolescents who completed the program and had a current phone number on file were contacted by ELSC staff & recruited to participate in the study as the intervention group.

Inclusion criteria for intervention group included youth who completed ELSC, defined as attending ≥75% of the classes and had complete baseline data available. Exclusion criteria for the intervention group included incomplete baseline data. Youth in the community who were seen in the clinic during the same time frame and recruited to participate in the program but did not complete the program were recruited as the control group. Inclusion criteria for the control group included youth recruited to ELSC but did not participate or did not complete at least 75% of the required classes. Exclusion criteria included anyone who completed the program.

Data collection

Once subjects were identified and recruited, they were scheduled to return to the clinic. Minor assents and parental permissions were obtained for all participants. Quantitative factors, such as HgbA1c, BMI and blood pressure were assessed. Participants also completed a health behavior survey on a computer using Qualtrics shown in Figure 1. The A1c was the preliminary outcome. The BMI, blood pressure and healthy behaviors were secondary outcomes. Thirty-four participants were needed in order to achieve a power of 0.8. There were twenty-one adolescents recruited as the intervention group and nine in the control group. Quantitative and qualitative follow up data for the intervention group were compared to data collected before and after completing the program (>2 yrs prior). BMI% and BP% are percentiles based on the child's age and height using charts established by the CDC (13).

Statistical Analysis

A matched analysis, Wilcoxon rank sum, was completed to compare the A1c%, BMI, BMI%, diastolic BP, diastolic BP%, systolic BP, and systolic BP%, and health behaviors for the intervention versus the control with A1c% as the primary outcome. With a statistical power of 80% and an alpha of 0.05, 34 patients were needed if the estimated mean difference of A1c is one unit between the intervention and control groups. 128 participants were needed if the estimated mean difference of A1c is 0.5 unit between the intervention and control groups with a statistical power of 80% and an alpha of 0.05.

A paired data analysis (Wilcoxon signed rank t-test) was used to compare the pre-intervention, post-intervention and follow up variables of A1c, BMI and BMI%. The primary outcome for our paired data analysis with this power and sample size calculation is the measurement of A1c. With a statistical power of 80% and an alpha of 0.05, 10 patients were needed if the estimated mean difference of A1c is 1 unit between pre and post intervention. Thirty-four patients were needed if the estimated mean difference of A1c is 0.5 unit pre/post intervention with a statistical power of 80% and an alpha of 0.05.

Figure 1: Health Behavior Survey

THE UNIVERSITY OF ARIZONA

English (US)

Default Question Block

What is your name?

Are you?

- Male
- Female

How old are you?

Each DAY, about how many times do you eat snacks like French fries, chips, cookies or candy?

- 7 times or more a day
- 4-6 times a day
- 2-3 times a day
- Once a day
- Never

Each DAY, about how many times do you drink soda, juice, Gatorade or other sweet beverages? (do not count 'diet' beverages)

- 7 times or more a day
- 4-6 times a day
- 2-3 times a day
- Once a day
- Never

How much soda or sweet beverage do you drink each time?

- A whole can/bottle
- A glass
- A half a glass
- None

Each DAY, about how many fruits and vegetables do you eat?

- More than 7 a day
- 4-6 a day
- 2-3 a day
- 1 a day
- None at all

Do you smoke?

- Yes
- No
- Sometimes

How many hours of physical activity do you do each day?

- More than 2 hours a day
- 2 hours a day
- 1 hour a day
- 30 minutes a day
- None at all

How many hours per day do you spend watching TV, using the computer, paying video games, or on the telephone?

- More than 2 hours a day
- 2 hours a day
- 1 hour a day
- 30 minutes a day
- None at all

Results

Participants

A total of thirty participants were recruited, twenty-one in the intervention group and nine in the control group. Subjects ranged between the ages of 10-17 with 63.3% being male. All participants had not been in contact with ELSC for over two years with some participants greater than four. Of the participants 68.2% had a family history of type 2 diabetes mellitus. See Table 1.

Survey Outcomes

In the survey, participants were asked how frequently they consumed unhealthy snacks such as French fries, chips, cookies or candy. We also asked how many sugar sweetened beverages they consumed such as sodas, Gatorade, juice and other sugar sweetened beverages. Physical activity was also measured along with smoking habits and screen time. Frequency of consuming fruits and vegetables was also measured. Using a Wilcoxon Rank Sum analysis, we compared the survey answers of the intervention group to the control group. No differences in healthy behaviors were observed between groups. The percent of responses for each answer in the survey are shown below in Figures 2 and 3. The figures, for the sake of simplicity, were split between eating behaviors and physical activity/screen time.

Table 1: Demographic Characteristics of the Participants			
Characteristic	All participants (N = 30)	Intervention Group (N = 21)	Control Group (N = 9)
Age group			
10-13	18 (60%)	14 (66.7%)	4 (44.4%)
14-17	12 (40%)	7 (33.3%)	5 (55.6%
Sex – No.			
Female	11 (36.7%)	7 (33.3%)	4 (44.4%)
Male	20 (63.3)	14 (66.7%)	5 (55.6%)
Months since program or last clinic visit			
0-24		1 (4.8%)	
25-48		12 (57.2%)	5 (62.5%)
>49		5 (23.8%)	3 (37.5%)
Family Hx of DM	N = 22	N = 14	N = 8
Yes	15 (68.2%)	11 (78.6%)	4 (50%)
No	7 (31.8%)	3 (21.4%)	4 (50%)

Figure 2: Survey Eating Behaviors

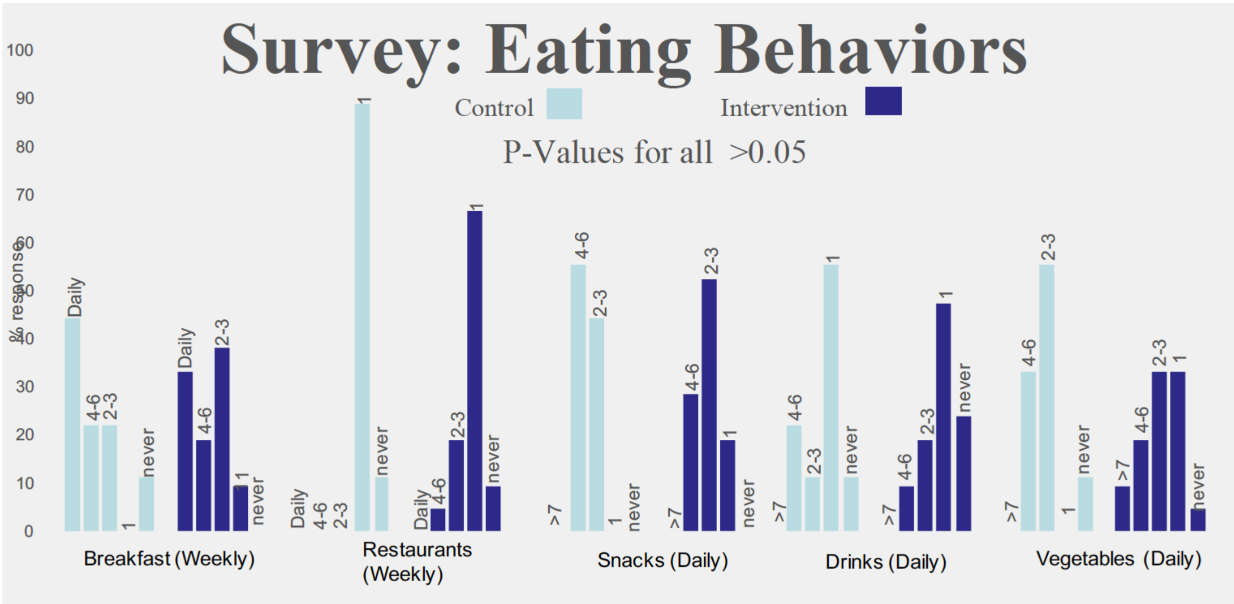
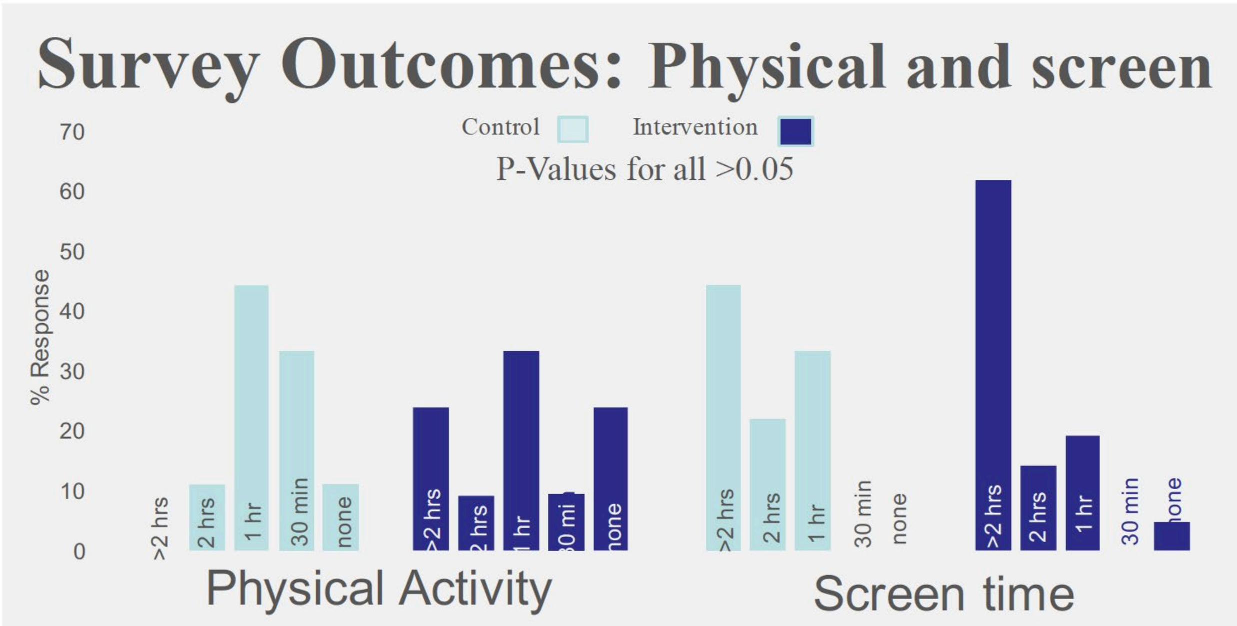


Figure 3: Survey Screen Time and Physical Activity



Biometric Data

There was no significant difference in many biometric factors in the intervention vs. the control. The median A1c% between the intervention was 5.1 versus 5.15 for the control. The median systolic BP was 121 for the intervention and 127.5 for the control while the median systolic BP% was 78% for the intervention and 93.5% for the control. These values, the A1c% ($p=0.87$), systolic BP ($p=0.21$), systolic BP% ($p=0.29$), and BMI% ($p=0.11$) were not significantly different between the intervention and control. The median diastolic BP was 68 for the intervention and 76 for the control. The median diastolic BP% was 57% for the intervention and 86% for the control. The median BMI for the intervention was 28.4 and 33.4 for the control. The median BMI% was 97% for the intervention and 99% for the control. These values, the diastolic BP ($p=0.02$), diastolic BP% ($p=0.04$) & BMI ($p=0.02$) were significantly lower in the intervention group compared with the control.

The intervention group, when compared to its previous baseline data demonstrated a statistically significant decrease in A1c% ($p=0.001$) overtime but a significant increase in BMI% ($p=0.01$). The median A1c% at baseline for the intervention group was 5.4 while the A1c% at follow-up was 5.1. The median BMI% at baseline was 88% while the BMI% at follow-up was increased to 97%. See Figures 4, 5, 6 and 7.

Figure 4: Hgb A1c overtime & intervention vs. control

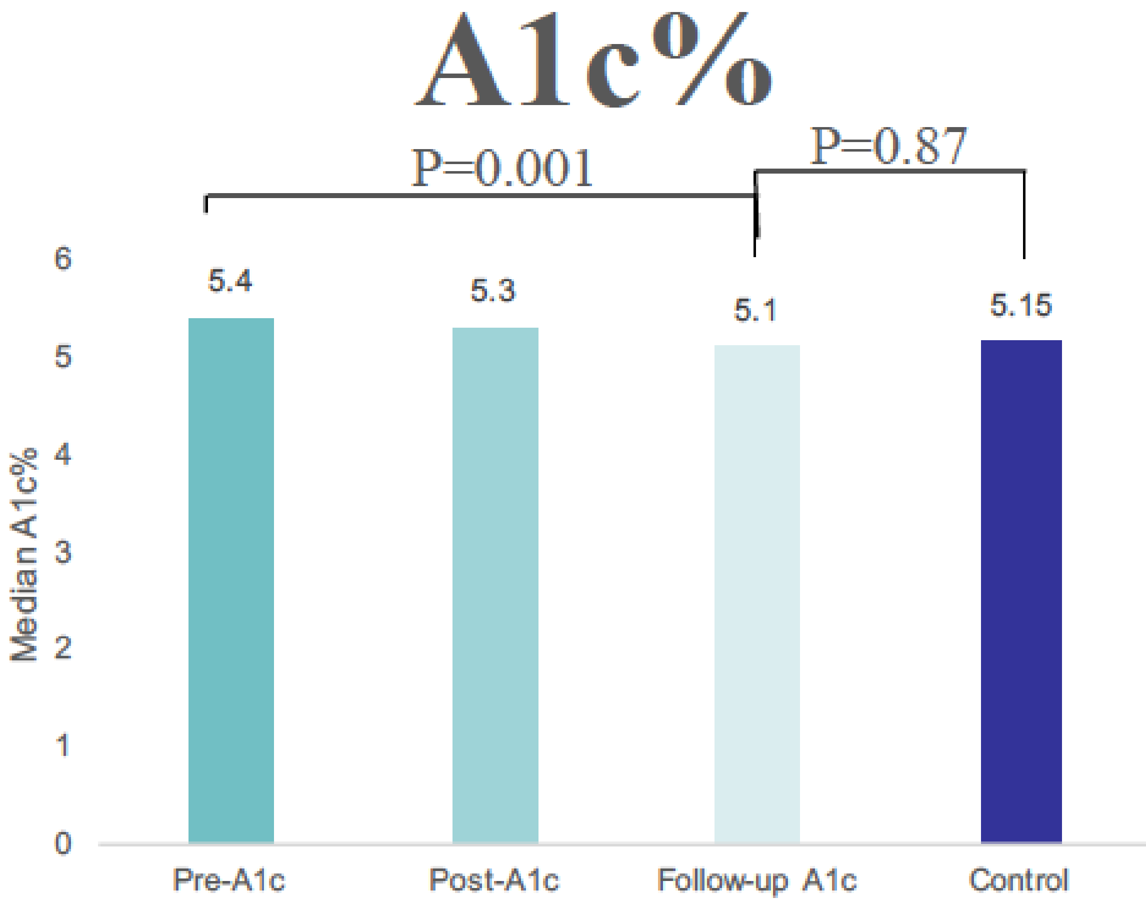


Figure 5: BMI% overtime & intervention vs. control

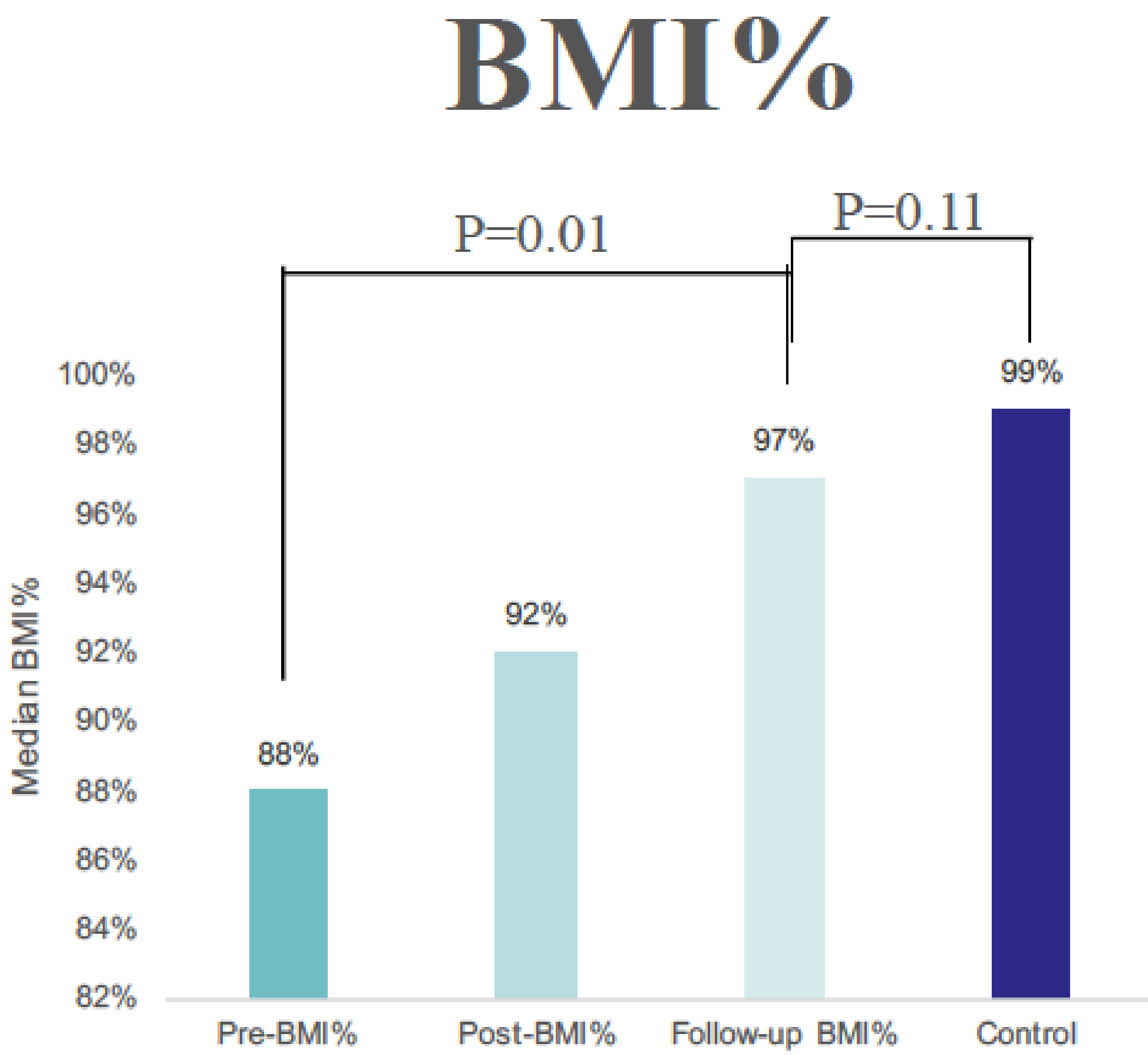
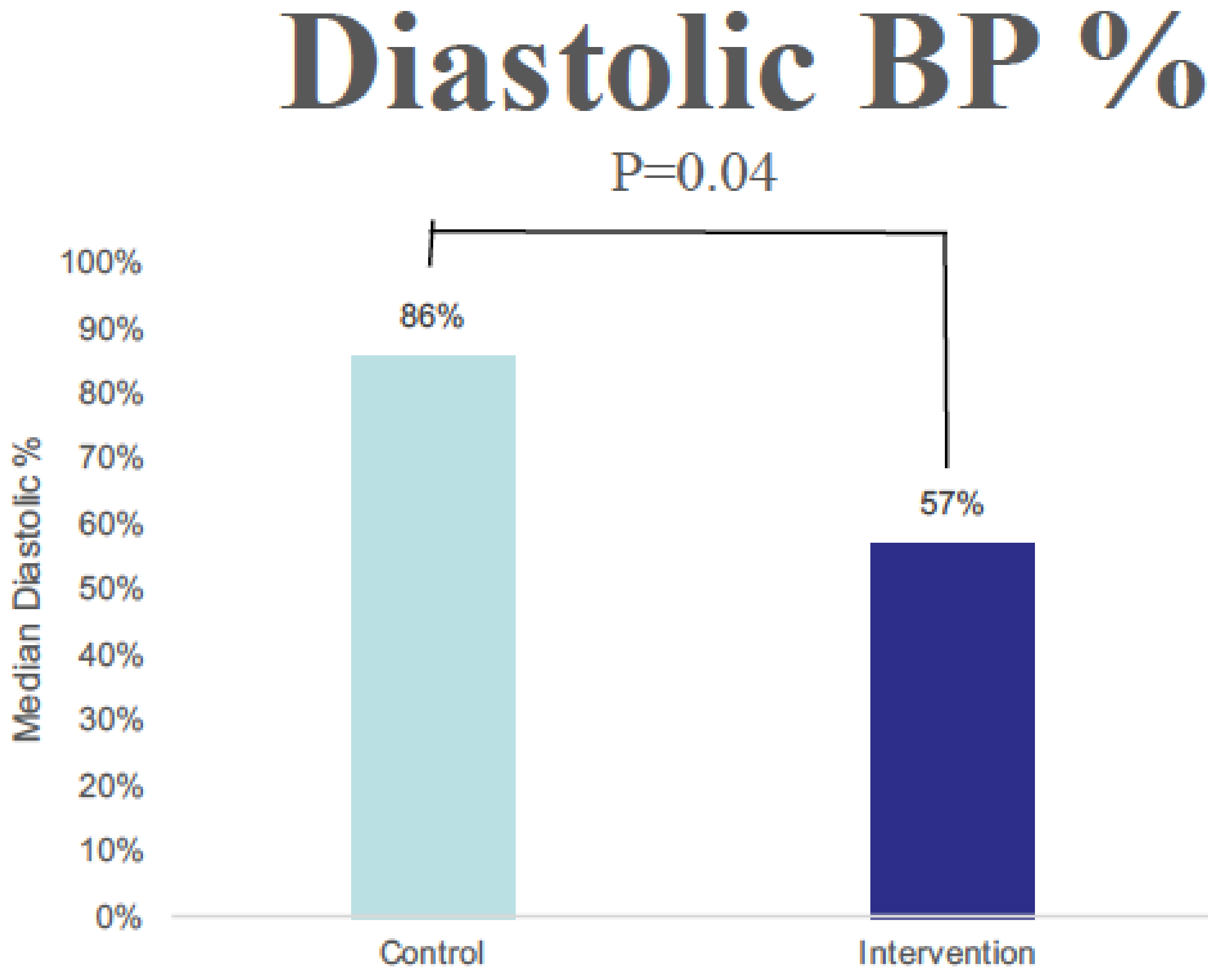


Figure 6: Diastolic BP% intervention vs. control



Discussion

The results of this study are conflicting and demonstrate the multifactorial complexity of diabetes, obesity and metabolic syndrome. The increasing BMI and lack of clinically significant difference in many of the biometrics would support that the program has not led to a difference in the risk of developing type II diabetes in this high-risk youth population. Confounding the data is the fact that adolescents in puberty are at a physiologic peak with insulin resistance, which could explain the decrease in A1c yet the increase in weight and BMI. On the other hand, the incidence of type II diabetes in this age group is so low that it was not expected that there would be a difference in patients converting to type II diabetes with a sample size as small as ours.

Following our initial findings, the Arizona State University Southwest Interdisciplinary Research Center, the entity that has performed data collection and analysis on the ELSC participants, was awarded an NIH grant for the follow up of the same population we studied. The grant funded a follow up study of the adolescents who completed the program and were five years post intervention, which continues for a five-year cohort. They measured many of the same biometric and lifestyle data as our study and had a much higher recruitment/retention rate. They did not have a control. Although their total N after the first year's follow up was lower than ours, they identified two participants that developed diabetes and had similar findings as ours in respect to weight gain and BMI.

We proposed that after completion of the ELSC program the participants would have continued points of contact at three, six and twelve months then annually until adulthood. During those points of contact or reunions they would get high yield take home points from the original curriculum, a cooking class and an exercise class while the same data on A1c, BP, BMI, etc. would be measured. During the first year of follow up a champion would be identified in each group and they would maintain contacts for the other participants and plan the future reunions. When this was proposed to SIRC, they informed us they had already implemented a similar model to this, except without the champions, and that multiple continued points of contact about weight loss were not effective.

Once the NIH funded study revealed two participants had developed type II diabetes, they organized a meeting of all of the stakeholders to brainstorm immediate changes to avoid similar results in the following four years follow up. It was unanimously decided that the participants were all aware of the principles of healthy living but did not have long term goals in their lives that they were working towards. Day to day life seemed to overshadow a reason to live healthier today to avoid health consequences in the future. There was a value in the multiple points of contact post intervention yet the content needed to be changed. As we proposed, a champion from the adolescent group would be identified and they would be responsible (with the help of mentors) to identify and recruit speakers from within their community who went on to work in careers in medicine, engineering, law enforcement, etc. The focus of the reunions would be more long-term life goals and the means for achieving them.

Another future direction to consider is incorporating mobile health delivery, such as mobile apps, games and text messages, to further improve outcomes among obese youth. It has potential to improve long term outcomes and can help reinforce the behaviors covered during the program. These mobile tools are important to consider when working with a pediatric population. Although this program is labeled as a medical and behavioral integrated model there is no evidence that the medical providers and the behavioral providers are in communication or using each other's information to formulate plans with their patients.

With childhood obesity on the rise and the associated negative health consequences emerging in younger patients many efforts have been made to address the problem. ELSC has offered programs to its population for several years now and based on both our findings along with the preliminary data through the NIH funded study we know changes need to occur in order to avoid the DARE phenomenon of widely adopted practices that did not lead to the proposed goal or behavior change.

Diabetes prevention programs in adults have been received with mixed views on its success as well. Although there is an initial benefit, the benefit on the incidence of diabetes wanes with time until at ten-years post intervention the incidence is the same whether you completed the program or not. If changing the name itself to diabetes delaying programs would lead to higher adoption rates, then in twenty years we will know if having completed a diabetes delaying program decreases the morbidity and morbidity of those affected by the disease.

It appears that the ELSC program is not effective at preventing diabetes in high risk adolescents. Time will tell if the ELSC program is successful at preventing co-morbidities related to being overweight and obese as many of the chronic diseases do not manifest until the fourth or fifth decade of life. More research following this high risk youth population into adulthood is needed to delineate it’s significant long term efficacy at preventing conversion to type II diabetes and other weight associated conditions.

Conclusion

The primary outcome in the evaluation of the long-term efficacy of an integrated behavioral and medical program in preventing diabetes in high risk youth was the development of type II diabetes. Secondary outcomes included changes in BMI, development of HTN and rates of adopted healthy behaviors. Compared to the control group, there were no significant statistical differences in hemoglobin A1c, systolic blood pressure (BP), systolic BP% , BMI%, or health behaviors. These findings are consistent with the program having no effect on improving HgbA1c or decreasing the BMI, markers most commonly followed for the development of diabetes. Although the results also demonstrated a statistically significant difference in diastolic BP, diastolic BP%, and absolute weight and BMI that favored the intervention group, these findings by themselves are not clinically significant and one cannot draw the conclusion that this particular program is effective.

The results comparing the pre and post intervention to their follow-up data demonstrated a statistically significant, yet non-clinically significant decrease in HgbA1c and a significant increase in BMI%. If the intervention was effective, the intervention group's BMI% would be significantly lower than the control regardless of the increase over time.

Limitations to this study included a small sample size, a short follow-up interval, poor data organization and communication with the program that delivers the curriculum as well as the program that performs their data collection and difficulty recruiting participants to return to the clinic. Additionally, given that the targeted population was young Hispanic at risk youth who are bilingual the findings are not generalizable.

References

1. Age-Adjusted Percentage of Adults Aged 18 Years or Older with Diagnosed Diabetes Who Were Overweight, United States, 1994–2010. *Centers for Disease Control and Prevention*. 2014. Available at: http://www.cdc.gov/diabetes/statistics/comp/fig7_overweight.htm. Accessed February 23, 2016.

2. Bluher S, Kromeyer-Hauschild K, Graf C, et al. Current guidelines to prevent obesity in childhood and adolescence. *Klin Padiatr*. 2015.

3. Cawley J, Meyerhoefer C. The medical care costs of obesity: An instrumental variables approach. *J Health Econ*. 2012;31(1):219-230.

4. Colditz GA, Willett WC, Rotnitzky A, Manson JE. Weight gain as a risk factor for clinical diabetes mellitus in women. Ann Intern Med. 1995; 122:481

5. Dabelea D, Mayer-Davis EJ, Saydah S, et al. Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *JAMA*. 2014;311(17):1778-1786.

6. de Onis M, Blossner M, Borghi E. Global prevalence and trends of overweight and obesity among preschool children. *Am J Clin Nutr*. 2010;92(5):1257-1264.

7. Flynn MA, McNeil DA, Maloff B, et al. Reducing obesity and related chronic disease risk in children and youth: A synthesis of evidence with 'best practice' recommendations. *Obes Rev*. 2006;7 Suppl 1:7-66.

8. Inge TH, Courcoulas AP, Jenkins TM, et al. Weight loss and health status 3 years after bariatric surgery in adolescents. *N Engl J Med*. 2016;374(2):113-123.

9. Liu LL, Lawrence JM, Davis C, et al. Prevalence of overweight and obesity in youth with diabetes in USA: The SEARCH for diabetes in youth study. *Pediatr Diabetes*. 2010;11(1):4-11.

10. Wang Y, Wu Y, Wilson RF, et al. Childhood Obesity Prevention Programs: Comparative Effectiveness Review and Meta-Analysis 2013.

11. Wang YC, McPherson K, Marsh T, Gortmaker SL, Brown M. Health and economic burden of the projected obesity trends in the USA and the UK. *Lancet*. 2011;378(9793):815-825.

12. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. (2009). *The Lancet,374*(9702), 1677-1686. doi:10.1016/s0140-6736(09)61457-4

13. Blood Pressure Levels for Boys by Age and Height Percentile. (n.d.). Retrieved from https://www.nhlbi.nih.gov/files/docs/guidelines/child_tbl.pdf