Abstract
With the significant increase in the number of racial/ethnic minority youth with obesity and type 2 diabetes mellitus (T2DM), effective approaches are urgently needed. Although previous school-based studies have demonstrated that programs combining environmental, behavioral and educational components can be successful in preventing cardiovascular disease in youth such studies have not focused on youth at higher risk for T2DM- inner city, racial/ethnic minority youth. Engaging in regular physical activity is widely accepted as an effective preventative measure for a variety of obesity-related chronic diseases including diabetes and metabolic syndrome. Disparities exist where racial/ethnic minority and low-income youth do not meet these physical activity recommendations. Schools, through the provision of culturally and developmentally appropriate healthy lifestyle programs, have the power to decrease body mass index (BMI) and increase physical activity, especially for racial/ethnic, inner-city at youth at risk for T2DM. The present clustered, randomized controlled trial study utilized a community-based participatory research approach to evaluate the impact of a family-centered, culturally sensitive, comprehensive school health program, called Kids N Fitness®, on BMI z-scores and physical activity behaviors of the youth participant from baseline to the 12-month follow-up among a sample of Mexican-American, inner-city elementary school youth (N = 97) in Los Angeles County at risk for T2DM. Results: Youth who participated in the KNF® program had significant decreases in BMI (p = 0.05), BMI body mass index z-scores (p = 0.03), vigorous daily physical activity (p = 0.01) and PE class attendance (p = 0.02) from baseline to the 12 month follow-up. Conclusions: These results suggest that a culturally appropriate, comprehensive school health program may have promise for decreasing BMI and BMI z-scores and increasing activity in this high risk sample. Clinicians and teachers can incorporate the approaches used in this study to reduce the risk of T2DM in youth at risk.

Keywords: At-risk youth; Obesity; Prevention; Racial/ethnic disparities; Type 2 diabetes mellitus

Abbreviations: BMI: Body Mass Index; CSHP: Coordinated School Health Program; KNF®: Kids N Fitness; T2DM: Type 2 diabetes mellitus

Introduction
With the significant increase in the number of racial/ethnic minority youth with obesity and type 2 diabetes mellitus (T2DM), effective approaches are urgently needed. Although previous school-based studies have demonstrated that programs combining environmental, behavioral and educational components can be successful in preventing cardiovascular disease in youth [1,2] such studies have not focused on youth at higher risk for T2DM in inner-city, racial/ethnic minority youth. Engaging in regular physical activity is widely accepted as an effective preventative measure for a variety of obesity-related chronic diseases including diabetes and metabolic syndrome. Disparities exist where racial/ethnic minority and low-income children do not meet these recommendations. Studies suggest that the greatest decrease in physical activities occurs during early to late adolescence, a critical period of child growth and development. This decrease correlates with the increasing number of youth who are overweight (Body Mass Index [BMI] ≥ 84th - 94th percentile) or obese (BMI ≥ 95th percentile) [3]. Globally, in 2010, approximately 42 million youth under the age of five were overweight [4], and in the United States, the percentage of overweight school-aged youth (aged 5-14 years) has doubled in the last 30 years, from 15% to 32% [5]. Obesity in youth is a strong predictor for obesity in adulthood, and obese youth are more likely to exhibit increased insulin levels and insulin resistance, indicating the need for early intervention to prevent progression to T2DM [6,7]. Recent estimates from a population-based study suggest high rates of racial/ethnic disparities, with higher prevalence seen in African-American youth (3.22 cases per 1000 youth) and Latino youth (2.18 cases per 1000 youth) [8]; and these rates are likely to increase with the rise in prevalence of obesity, particularly in racial/ethnic minority youth and those living in urban, low-income communities [9-11].

Comprehensive school health programs and prevention of T2DM
Given the rapid rise in obesity among youth, researchers have focused on developing comprehensive programs with the goal of reducing or preventing increases in BMI. A Cochrane review of 64 randomized clinical interventions designed to treat obesity in youth concluded that behavior lifestyle interventions had a significant effect on reducing BMI in youth up to 12 months post-intervention, noting that the most effective interventions combined dietary, physical activity and behavioral components [12]. Schools serve as an excellent venue to provide students with the opportunity for daily physical activity and to teach the importance of regular physical activity and a healthy diet in order to build skills that support active lifestyles [13-15] and decrease their risk for T2DM. Schools have access to school nurses who can provide screening, counseling and continuum of care [13-15]. In contrast to clinical programs, school programs can be delivered
at little or no cost to families and can reach low-income urban youth who otherwise might not receive treatment. School-based obesity prevention programs are most effective if they follow a coordinated, comprehensive program for school health (CSHP) that combines dietary guidelines, physical activity and school-based or environmental activities [16]. These findings suggest the promise of comprehensive interventions, while highlighting the need for innovative approaches for youth at risk for T2DM, particularly Latino youth who may be at the highest risk due to the high rates of obesity in this population [17].

Increasing physical activity ≥ 60 minutes per day is a recommended goal in childhood obesity prevention and treatment [18,19]. Despite this recommendation, there is a relative paucity of published studies that assess the impact that comprehensive school-based obesity prevention programs have, especially on reducing BMI and increasing physical among urban, low-income, youth at risk for T2DM. In this paper, we report the results of a randomized control trial of a program to reduce the risk of T2DM in inner-city racial/ethnic minority youth. Recent studies suggest racial and income disparities in T2DM exist, in that as many as 50% of racial/ethnic minority, inner-city youth are obese and that the rate of T2DM in these communities is increasing at a rapid rate [17]. The purpose of this randomized control study was to examine the impact of a culturally and linguistically appropriate after-school, family-focused, CSHP on BMI z-scores and physical activity behaviors of the youth participant from pre-intervention to the 12-month follow-up among a sample of Mexican-American, inner-city elementary school-aged youth. Future papers will report on youth dietary behaviors. We hypothesized that intervention participants would have sustained weight loss, as indicated by decreasing BMI z-scores, and would have sustained increases in daily physical activity.

Materials and Methods

Participants

A larger study of 251 youth was conducted and participants were English or Spanish speaking, had a BMI between the 85th and 94th percentile, were between 8-12 years of age and had no physical limitations that prevented regular exercise. After baseline screening, 97 Mexican-American youth were found to be at risk for T2DM, (e.g., a BMI ≥ 85th percentile and with a parent who self-reported having T2DM). This paper focuses on these at risk youth (N = 97). Youth and their parents assented/consented to participate in line with institutional ethical and research governing body.

Intervention fidelity

Once approved by the CAB, research team members were trained on all aspects of the intervention. To ensure fidelity of the intervention, team members were trained to implement protocols through full-day in-person training. They used a checklist of the course contents to ensure that protocols were consistently followed. They also rated how well the material was covered. The checklist was used during classroom observations. If research team members were not following the protocol they were given assistance and, if necessary, retrained (< 10% of classes).

The Kids n fitness (KNF) program

KNF® is a 6-week after-school program for parents and their youth, with weekly 90-minute sessions conducted by a registered nurse, trained community health workers, and a physical education

Students were compensated for their time with small tokens (stickers and/or a small toy). Parents were compensated for their time with a small token ($10 grocery store gift card). The study was approved by the University of California Los Angeles Institutional Review Board, the ethical and research governing body.

Once enrolled schools were randomly assigned to either the Kids N Fitness® intervention group (KNF®) (2 schools) or to the general education (GE) group (3 schools) utilizing urn randomization [20]. To ensure balancing of groups, the urn randomization was based on baseline characteristics including gender, race and SES. The general education group participated in the standard physical activity program given by their respective schools and did not receive any physical or nutritional education. The KNF® intervention group had two components, a family-centered educational lifestyle program plus environmental interventions at the school site. The intervention components were developed by the study team, which included a nutritionist, an advanced practice nurse, registered nurses, an exercise physiologist, a psychologist, and trained community health workers from the local schools. Once developed, it was reviewed by the CAB and pre-tested with 25 youth, who also provided cultural and linguistic modifications.

Procedure

The study was a parallel-group, cluster, randomized control trial. Between January 2008 and September 2010, students were recruited from five underserved elementary schools in Los Angeles, CA. Between January and April 2008, letters were sent to all elementary schools in the downtown Los Angeles area. Schools were similar in ethnicity, gender breakdown, and SES (as measured by percent use of the free/reduced meal program), whereas all schools had a student population of at least 50% utilizing the free/reduced cost meals program (Figure 1). The first five schools that responded to the letter and signed a Memorandum of Understanding (MOU) created by the Community Advisory Board (CAB) were enrolled in the study. The study design included repeated measures at the individual student level, where questionnaire data and anthropometric measures were collected by trained research staff at the school sites at baseline (pre-intervention), at the completion of the intervention phase (4 months), and at 12 months post-intervention.

Figure 1: Consort Table - Flow diagram of recruitment and attendance.
Environmental activities: school and community involvement

Environmental interventions at the school/community-level included (1) establishing partnerships with local community clinics who provided on-site health and mental health services for the youth; (2) a School Health Advisory Council (Advisory Council) made up of representatives from the University, school administrators and staff, parents and community partners that created and promoted School Wellness Policies involving physical activity and dietary changes; (3) staff professional development seminars taught by research team members on nutrition and activity; and (4) home-level activities that included parental outreach via bi-monthly educational newsletters created by the Advisory Council that were mailed to parents’ homes.

Measurements and Instruments

Data were collected using the following instruments.

Demographics

Parents/Guardians completed a demographic form utilizing questions from the 2006 Behavioral Risk Factor Surveillance System Questionnaire (BRFSS), which included race/ethnicity, marital status, education level, income level, health status, youth diagnosed by an MD with asthma, and youth still with asthma. Youth completed the demographic section of the Child and Adolescent Trial for Cardiovascular Health (CATCH) Health Behavior Questionnaire (includes the CATCH School Physical Activity and Nutrition (SPAN) Student Questionnaire), which included questions on date of birth, age, gender, primary language spoken, and race/ethnicity (Table 1). Questionnaires were in both English and Spanish.

Body Composition

Subjects’ weight measurements were obtained to the nearest 0.1 kg using a Detecto electronic weight scale that was calibrated daily. Heights were measured in 0.1 cm increments using a Harpenden stadiometer. BMI values (kg/m²) and associated z-scores were calculated using Epi Info software developed by the CDC [3].

Anthropometric measures

Resting blood pressure was obtained via the LifeSource UA-100 Aneroid sphygmomanometer, which was calibrated prior to measurements (utilizing appropriate pediatric or adult-sized cuffs). To measure waist circumference, a cloth tape measure was placed around the abdomen horizontally at the midpoint between the highest point of the iliac crest and the lowest point of the costal margin in the mid-axillary line. Measurements were performed three times and averaged for analyses.

Physical activity behaviors

Physical activity behaviors from a modified CATCH SPAN Questionnaire included daily vigorous physical activity, PE class

| KNF Group (n = 121) | GE Group (n = 130) | p-value* |
|-------------------|-------------------|----------|
| Age, mean (SD)    | 9.9 (1.6)         | 9.3 (1.1) | 0.18     |
| Grade, Mean (SD)  | 4.5 (1.2)         | 4.1 (1.5) | 0.02     |
| Gender*           |                   | 0.04     |
| Male, N (%)       | 15 (30)           | 12 (25)  |          |
| Female, N (%)     | 34 (70)           | 36 (75)  |          |
| Primary Spanish Speaking, N (%) | 38 (77) | 34 (70) | 0.01     |
| Diagnosed with Asthma, N (%) | 5 (10) | 6 (12) | 0.34     |
| Child Race/Ethnicity, N (%) | 0.01   |          |          |
| Hispanic/Latino   | 49 (100)          | 48 (100) |          |
| Mexican/Mexican American | 49 (100) | 48 (100) |          |
| Caregiver Gender - Female | 49 (100) | 48 (100) | 0.33     |
| Caregiver Education, N (%) |                   | 0.02     |
| 1-8th grade       | 12 (24)           | 11 (22)  |          |
| 9-11th grade      | 21 (44)           | 15 (31)  |          |
| Grade 12 or GED   | 16 (33)           | 22 (45)  |          |
| College 1-4 years | 0 (0)             | 1 (2)    | 0.03     |
| Caregiver Marital Status, N (%) | 0.03   |          |          |
| Single Parent Household* | 21 (40) | 21 (42) |          |
| Married           | 28 (60)           | 27 (58)  |          |
| Caregiver Income, N (%) | 0.01    |          |          |
| 0-$15K            | 27 (55)           | 29 (60)  |          |
| $15K-$25K         | 22 (45)           | 19 (40)  |          |

*P <.05 by from t test (age and grade) or χ² (all others)

Table 1: Baseline (Pre-Intervention) Demographic Characteristics by Group.
attendance and team sports participation. Internal consistency for activity behavior questions was α = 85.

Data analysis

Baseline characteristics were compared using t-tests for continuous variables and chi-square tests for categorical variables. Data were analyzed under the intent-to-treat principle whereby all randomized subjects were analyzed in the group to which they were randomized [21]. The intent-to-treat analysis was performed on all 97 randomized subjects. This included 3 youth who were randomized and participated in the intervention but were lost to follow-up. For the primary analysis, a mixed model of repeated measures analysis (adjusted for baseline scores, youth’s race, and parental marital status) was used to evaluate changes in outcomes over time and to compare these changes between KNF© and GE groups. This model provides unbiased estimates of time and treatment differences in outcomes, assuming missing data are missing at random (MAR) [22], i.e., given the observed outcomes and covariates, missing data are not dependent on unobserved values [23]. Predicted least square means was used to calculate changes from baseline to 4 months and 12 months in each outcome of interest over time across both groups and by groups. A p-value of ≤ 0.05 was deemed significant. All analyses were performed in SAS V9.1 [24].

Results

Demographics

Of the 49 students initially enrolled in the KNF© program, all (100%) attended at least half of the sessions and therefore constituted the study cohort. There were 49 students assessed at baseline in the KNF© group and 48 in the GE group. Both groups were similar in that there were more girls, more students from the 4th grade, and between 10%-12% had co-morbid condition of asthma. Regarding the parents, more parents in the GE group had a high-school level education and had an annual income at or below the federal poverty level of 0-$15K/year (Table 1).

Three youth (6%) were lost to follow-up at 12 months in the KNF© group, compared to two youth (4%) in the GE group (p = 0.75). Youth who were lost to follow-up, compared to those who completed the study, were more likely to be older (48.2% vs. 46.3%) and were Spanish-speaking students (58% vs. 52%) (p = 0.02).

Anthropometric outcomes

There were no significant baseline anthropometric group differences between the KNF© and GE Groups (Table 2). However, there was a significant decrease between the KNF© and GE groups. In the KNF© group from baseline to 4 months, and the effect was sustained at 12 months, for BMI there was a group difference of – 1.28 (p = 0.04) and BMI z-score difference of -0.95 (p = 0.03).

Physical activity

At baseline, there were significant group differences for vigorous daily physical activity (p = 0.03), PE class attendance (p = 0.02), and sports team participation (p = 0.03) (Table 2). There were significant increases from baseline to 4 months and the effect was sustained at 12 months (Table 3) for vigorous daily physical activity, an increase of 1.89 (p = 0.01) and an increase of 1.20 (p = 0.02) for PE class attendance, but not for sports team participation. As compared to English speakers, Spanish-speaking students had significant increases from baseline to 12 months in vigorous daily physical activity of 0.98 (p = 0.02) (Results not shown). Youth with the co-morbid condition of asthma had significant increases in PE class attendance from baseline to 12 months, 0.78 (p = 0.05), but not in daily vigorous physical activity or sports team participation (results not shown).

Discussion

Obesity is a risk factor for the development of T2DM during childhood, a disorder that is now epidemic in Latino and African-American youth. Further, obesity is a risk factor for poorer health outcome, decrease self-efficacy, depression, and poor academic success [25,26]. Given the huge economic toll created by obesity and T2DM, interventions that prevent both illnesses are needed. Therefore, this study was designed to address these gaps in knowledge by furthering our understanding of the potential for a culturally and linguistically appropriate, comprehensive school health program to manage obesity and prevent further exacerbation of the illness, particularly T2DM among a cohort of inner-city, Mexican-American youth. This study is unique in that it is one of few studies in this population that showed sustained improvements over a 12-month period of time. All intervention participants fulfilled the hypotheses of sustaining substantial weight loss, as indicated by BMI z-scores and increasing vigorous daily activity. These results suggest that a comprehensive school health program has promise for decreasing BMI and BMI

|                      | KNF© Group Pre-Intervention (N = 121) | GE Group Pre-Intervention (N = 130) | p-value* |
|----------------------|--------------------------------------|------------------------------------|----------|
|                      | Mean (SD)                            | Mean (SD)                          |          |
| **Anthropometric measures** |                                      |                                   |          |
| BMI (kg/m²)*        | 21.89 (6.26)                         | 21.25 (6.68)                       | 0.06     |
| BMI Z-score*        | .98 (.50)                            | 1.90 (.76)                         | 0.08     |
| Waist Circumference | 26.91 (4.16)                         | 26.82 (3.91)                       | 0.89     |
| **Physical Activity** |                                      |                                   |          |
| Vigorous daily PA*  | 1.21 (.50)                           | 1.25 (.69)                         | 0.03     |
| Participation in Team | 1.34 (.47)                        | 1.32 (.40)                         | 0.03     |
| Sports**            | .64 (.70)                            | .56 (.65)                          |          |
| Attend PE Class†    | 1.01 (.41)                           | 1.10 (.49)                         | 0.02     |

*BMI- Body Mass Index  
**P < 0.05 by t test  
*PA = Physical Activity  
*On how many days of the past 7 days did you exercise or take part in physical activity that made your heart beat fast and made you breathe hard for at least 60 minutes?” (Source: CATCH SPAN)  
**During the past 12 months, on how many sports teams did you play”? (Source: CATCH SPAN)  
†Last week, on how many days did you go to physical education (PE) or gym classes? (Source: CATCH SPAN)  

Table 2: Baseline Outcome Data between KNF© Intervention and GE Groups.
z-scores in this high-risk sample, but that future work is needed to find ways to engage youth and increase attendance.

These results are partially shared in the literature [18,27-30]. One school-based program among Mexican-American youth at risk for T2DM, similar to this study, shows the importance of creating a comprehensive network of activities in the classroom, the home, and the school environment, with these schools having youth with improved physical fitness and reduced body fat [31]. Another study among Latino and African youth at risk for T2DM utilized a school-based program that included nutrition and physical activity education and coping skills training found decreases in BMI, plasma glucose and depression [30]. Additional school-based intervention studies with youth in grades 2-4 showed similar post-intervention results of youth in the intervention group, with statistically significant relative decreases in BMI [18,27]; however, the studies showed no changes in PE class attendance [18,28].

Differences between the current study and the literature may be due to differences in the study population. For example, some studies focused only on African-Americans or only on girls [27]. The differences may also be related to varying intervention components. Some studies focused on an intervention that utilized a promotora or community-health worker only model [29]. Other studies focused their intervention on one specific form of activity, such as dance [27]; others used a combination of 2-3 activities [31,32]. One study included multiple components, including the environmental activity of a school-based committee, to assist with recommendations for improvements in nutrition and physical activity [33]. However, the current study utilized several key components in their education including mild, moderate and vigorous physical activity, nutrition education for parents and youth, and environmental activities that focused on educating teachers, school administrators, and parents and creating policy changes to meet the desired outcomes. Strength of this study was working with the teachers and administrators and parent-helpers in the schools, which had the advantage of more rapid adoption in the community, and the opportunity to "reach youth where they are" [34]. On the other hand, school-based interventions have the challenge of influencing the home environment in a large and significant way [35]. Future studies are needed to determine strategies to influence the home environment.

There are some limitations that should be taken into account in the interpretation of the data. First, the sample population was predominately Latino, therefore the generalizability to other racial/ethnic and regional groups may be limited, and future studies should be done in various racial/ethnic groups to assess changes in BMI z-scores and activity behaviors. The addition of metabolic and lipid measures may have added another dimension to the study; however, due to lack of permission from the schools to collect laboratory samples, we were unable to gather this data. Future studies should look at the impact of the intervention on metabolic and lipid measures. A major limitation of the study was the enrollment and retention of participants, especially at the 12-month follow-up period. Poor retention is a common phenomenon in many healthy-living programs in both youth and adults, especially among racial/ethnic minority populations [36]. There are several possible reasons for this low participation and retention in attendance. The schools involved were in the inner city, with low test scores in reading and math and high absenteeism. Students routinely were pulled from after school programs to attend tutorial reading and math classes in order to improve mastery test scores. In addition, coming from low SES schools, students and parents were not given monetary incentives, and parents who needed to work had to rush home from work to participate in the after school program, making it difficult for them to attend. The programs were funded through research grants, and perhaps schools and their community partners could come up with additional incentives that might encourage more parent participation.

Conclusions

This cluster, randomized control trial of a comprehensive school health program suggests that nurses and community health workers can deliver such an intervention successfully having received training from expert staff. In addition, inner-city minority youth, traditionally a difficult population to engage, participated in the program, with the majority successfully completing the study. Importantly, the literature recommends that population-based interventions directed towards childhood obesity prevention should target physical activity. The current study concurs with this recommendation and shows that a comprehensive, culturally and linguistically appropriate school-based intervention, which includes physical activity and nutrition education, can not only increase vigorous daily physical activity and increase PE class attendance, but also can decrease BMI and BMI z-scores. Clinicians and teachers can incorporate the approaches used in this study to reduce the risk of T2DM in youth at risk.

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