**South Texas Early Prevention Studies PreK**

**Study Design and Protocol**

**September 28, 2018**

**Study Design and Participants**
The STEPS-PreK4 was a CRT where preschools, embedded within elementary schools, were the unit of randomization, intervention, and analysis. The study was designed for two years of intervention (pre-kinder to kindergarten) and four data collection periods (fall 2018, spring 2019, fall 2019, and spring 2020). Due to the COVID-19 pandemic the study was stopped prematurely and only results from the first three periods will be presented.

The two school districts where the study was conducted are located along the Texas-Mexico border in the county of Hidalgo. These school districts were selected because of the high poverty and health risk-factors levels.[25] The preschools have two grade levels with children 3 and 4 years of age. The present study targeted preschools with children 4 years of age. Demographics of the two school districts were similar, 99% Hispanic, 92% economically disadvantaged, and 42% identified as English as a second language.

**Intervention**
The BN CHSP is a Texas Education Agency (TEA)-approved CSHP. This health program was first piloted in schools located in low-income neighborhoods where enrollment was predominantly Black and Latino children. For this reason, the curricula were given the name Bienestar/NEEMA. *Bienestar* and *NEEMA* mean well-being in Spanish and Swahili, respectively. TEA-approved CSHP aims is to control and prevent childhood obesity, youth-onset type 2 diabetes, and cardiovascular disease by providing instruction in health, nutrition, physical education, and chronic disease knowledge across several environments.

The Social-Ecological Model guided the BN CSHP design. This theory postulates that health behaviors are molded by individual, interpersonal, and environmental interactions. Thus, BN CSHP encompasses curricula from preschool to eighth grade and is designed to target the four environments that influence children's health behaviors: 1) *Healthy Lifestyles Healthy Minds* (Health), 2) *Moving For Life* (Physical Education), 3) *Eat to Live (*Child Nutrition/School Food Service), and 4) *MyFamily/MiFamilia (*Home). **Table 1** shows the preschool health education components of both treatment arms.

**Measures**
*Household characteristics*. Family Demographic and Household Health Characteristic questionnaires were sent to parents/guardians through 4 modes: online, face-to-face, school parent liaisons, and children. English and Spanish questionnaires collected information on age, gender, race/ethnicity, educational attainment, household income, persons living per household, physical activity, sedentary lifestyles, and family (1st and 2nd degree) history of hypertension and diabetes.

*PACER Fitness Test.* The PACER fitness test is a multistage shuttle run designed to measure CRF.[26] The objective of the PACER is to run as long as possible while keeping a specified pace. Children run back and forth across a 20-meter course at a tempo that gets faster each minute paced by an audio signal. For this study, the PACER test was

adapted for preschool children by adjusting the course to a 15-meter distance and using a 20-meter cadence. The test begins at a slow pace and each minute the pace increases. Beeps on the soundtrack indicate when a student should reach one end of the course where they stop and wait for the next beep. Children continue running until the pace can no longer be sustained for two laps. As soon as children stop running, their number of laps are recorded.

**Sample Size Calculation**
The sample size for the primary endpoint, obesity prevalence, assumed a 5% obesity rate decrease in the intervention compared to control group, a SD of 1.4, an intra-cluster correlation coefficient of 0.01, 70% response rate, and an attrition rate of 16 percent. [source: LJ ISD, PSJA ISD] A total of 28 preschools (clusters) with a mean cluster size of 49 children per school was estimated to detect the effect size with 80% power at a significant level of $\alpha = 0.05$. The calculated sample size was enough for a difference of at least 4.5 laps between treatments (secondary outcome) and the statistical power was 82% for alpha 0.05 with sample size of 40 children per cluster.