The Children in Action Pilot Study

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Abstract: Interventions that can successfully alter the trajectory toward obesity among high-risk children are critical if we are to effectively address this public health crisis. The goal of this pilot study was to implement and evaluate an innovative physical activity program with Hispanic-American (HA) preschool children attending Head Start. The Children in Action (CIA) program was a five month physical activity intervention. This intervention was a pilot study with 3- to 5-year-olds enrolled in four HA Head Start centers. After baseline assessment, centers were matched by enrollment and randomly assigned to either the intervention or the control condition. A total of 295 preschool children were randomly selected across the four centers. The primary endpoints of this study were favorable changes in physical activity levels and gross motor skills. Using mixed effect time-series regression models, changes in weight was a secondary endpoint. We did not observe a statistical difference between intervention and control groups in physical activity levels during the awake time, gross motor skills, or weight status. Process evaluation data showed that there was adherence to protocols and the intervention was delivered 92% of the time, four times per week, during the five month intervention. We demonstrated that it is feasible to conduct the SPARK-Early Childhood (EC) curriculum among preschool children attending Head Start centers but that an increased dose and/or longer intervention duration will be required to impact gross motor skills, physical activity levels and weight status during this critical early childhood development stage.

Keywords: Physical activity, children, Head Start, SPARK-EC.

INTRODUCTION

Regular physical activity is essential to the maintenance of a healthy weight. Research has documented that physical activity tends to track in early childhood [1-4] meaning that those who are physically active during early childhood are more likely to be physically active during later childhood. Physical inactivity, limited playtime outdoors, has been associated with increased risk of being overweight as early as 3 years of age [5-7]. The Institute of Medicine recommends that child care providers should provide preschoolers with "opportunities for light, moderate, and vigorous physical activity for at least 15 minutes per hour while children are in care"[8]. This corresponds to approximately three hours of physical activity over a period of 12 waking hours [8, 9]. Several systematic reviews indicate that preschoolers fail to achieve national guidelines for daily physical activity [10-12]. Evidence suggests that 3- to 4-year-old children spend only 20-25 minutes per day in MVPA [13-16].

Preliminary data show that preschool children are spending 27% of their awake time in sedentary activities [17]. These results are similar to those of Reilly and colleagues [18], who found that approximately 25% of minutes monitored were spent in sedentary behavior. However, the ability to accurately estimate preschooler's physical activity remains elusive until universally accepted cut points for accelerometer-derived estimates of physical activity are established [10, 19]. For this study, we developed Actical accelerometer thresholds for preschool-aged children using room calorimetry [20]. Children in full-time daycare settings do not engage in adequate amounts of physical activity on a daily basis [11, 21]. Directly observed physical activity levels in preschool children reported that children attending preschools engaged in moderate-to-vigorous physical activity during less than 3% of the observation intervals and were sedentary during more than 80% of the observation intervals [21]. DuRant and colleagues observed that the mean hourly activity levels of preschool children remained fairly constant throughout the day [22]. He also reported that some of the highest activity levels observed for preschool children were from 4-7 pm [22] . Our data showed comparable results in that the highest percentage of light and moderate activity was between 3-6 pm during the weekdays. The percentage of time engaged in MVPA during recess time at school accounted for a small amount of the daily MVPA [23] (< 12%). Studies suggest that school recess time is an important setting to promote MVPA and contributes to daily physical activity in young children [17, 24]. Children's physical activity levels are highly variable among preschool centers [25], suggesting that preschool program policies and practices have an important influence on the overall activity levels of the children the preschools serve [17, 26-29].

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Trial Registration
Current Controlled Trials: NCT01697124.

Teacher-led structured physical activities integrated in the preschool curriculum has the potential to decrease daily sedentary time and increase daily physical activity in preschool children [30]. The Children in Action (CIA) program was designed as a physical activity change intervention targeted at preschool children. The goal of this pilot study was to implement and evaluate an innovative physical activity program (i.e., SPARK-EC) with Hispanic-American (HA) preschool children in a Head Start (HS) setting. The physical activity program focused on the development of motor skills, movement knowledge, physical activity engagement and development of social and personal skills at an early age. Active engagement and practices in a positive, non-threatening environment are the means for improving children's personal enjoyment and physical and social development, thus increasing physical activity. The primary endpoints of this study were favorable changes in levels of moderate-vigorous physical activity (MVPA) and gross motor skills. Changes in weight were a secondary endpoint. The two primary hypotheses that were tested included: 1) children who received the CIA program would demonstrate increased MVPA compared to children in the control group and, 2) children who received the CIA program would demonstrate increased gross motor skills compared to children in the control group.

SUBJECTS AND METHODS

Study Overview, Population, and Analytic Sample

This intervention was a pilot study with 3- to 5-year-olds enrolled in 4 HS centers (predominantly HA). After baseline assessment, centers were matched by enrollment and randomly assigned to either the intervention (2 centers) or the control condition (2 centers).

For the four HA centers, two centers were randomly selected to receive the SPARK-EC program (intervention) and two to receive only supervised recess (control). All of the centers had five classrooms each (total n=20; 10 intervention and 10 control). All 10 classrooms in the two intervention centers participated in the intervention. The control centers received the SPARK-EC curriculum and the equipment after the intervention was completed. A total of 295 preschool children were randomly selected across the four centers. This study was conducted in accordance to the guidelines laid down in the Helsinki Declaration [31] and all procedures involving human subjects were approved by the Institutional Review Board of Baylor College of Medicine. Written informed consent was obtained from all subjects.

Conceptual Model

The original SPARK (Sports, Play, and Active Recreation for Kids) program, developed for elementary school children, resulted in children being physically active for more time during physical education classes [24, 32]. The original SPARK program was based on Social Cognitive Theory and was used as the foundation for developing the SPARK Early Childhood (EC) program. The SPARK-EC program was developed for ages 3-5 to provide early childhood professionals with the tools necessary to implement a quality movement program with their preschool children that will increase physical activity levels for a basic foundation of lifetime wellness.

Early childhood forms a unique period where children undergo significant social, intellectual, emotional, and physical development. Enhancement of movement skills is believed to play an important role in the development of children within the physical domain, with potential carry-over into the social and cognitive domains [33]. Body management activities, manipulation opportunities with a variety of equipment, and both locomotor and non-locomotor activities should form the basis of a young child's pre-school movement experience [34-36].

Fundamental movement skills are basic movement patterns that can be adapted, combined and refined to provide a foundation from which more complicated skills can be established and later applied to lifetime sporting, recreational, and physical activities [35, 36]. Fundamental movement skill (catch, throw, kick and the like) competency amongst primary school-aged children is considered by some to be poor [37, 38]. Because success is a strong predictor of motivation to participate and persist in sports, it is essential that young children be provided with opportunities to establish appropriate movement skill competencies at an early age [38-40]. Without those competencies children are less likely to participate in physical activity as they get older. Okley, Booth, and Patterson [41] found fundamental movement skill proficiency among other things, to be significantly associated with adolescents' participation in organized physical activity.

Intervention

The CIA study was a five month physical activity change intervention that utilized the SPARK-EC

curriculum as the intervention. The SPARK-EC curriculum was designed to be a quality, comprehensive physical activity program for the preschool setting. SPARK-EC focused on the development of motor skills, movement knowledge, physical activity engagement *(moderate-to-vigorous)* to promote healthy lifestyles, and development of social and personal skills during the critical early childhood development stage. The SPARK-EC curriculum, 15-20 minutes per day, three days per week was designed to be implemented by the HS teachers and aides and one day a week trained research staff conducted the lesson by themselves. Research staff members were trained to be facilitators who provided on site support to the intervention teachers/aides throughout the intervention. The intervention centers also received all of the equipment needed to conduct the lessons.

SPARK-EC Curriculum

SPARK-EC curriculum for preschoolers offered instruction and practice in a comprehensive program designed to promote motor development through increased physical activity. SPARK-EC included only activities that can be realistically implemented in a variety of preschool settings, including those that have limited space, equipment, and supplies. The activities have been field-tested and researched with preschool classes. Only activities that were manageable in diverse settings and produced substantial opportunities for children to actively engage in learning through movement were included. The activities could be conducted either indoors or outdoors.

SPARK-EC recommends a warm-up period, beginning with low intensity movement that gradually evolves into higher intensity engagement in a fun way (e.g., children can begin by walking in their play area and then progress to a gallop followed by a slow jog). The first instructional unit in SPARK-EC is "Movin' Magic." In this unit, short, quick songs prepare children for movement. This unit establishes a positive learning environment, behavioral expectations of children as well as management and organizational protocols. This unit also teaches concepts, principles, and techniques that provide the foundation of motor development. The SPARK-EC instructional units and the major physical/social parameters emphasized in each are outlined in Table 1.

After "Movin' Magic", lessons were selected from different units. A typical 15-20 minute SPARK-EC lesson consisted of two parts: 1) Good Vibrations (warm-up) with a transition to a main activity (2-3 min.), and, 2) Main activity *(moderate-to-vigorous physical activity)* with a transition to closure/cool-down (12-18 min.) Good Vibrations were introductory activities designed to prepare for movement. This type of activity

Table 1: SPARK-EC Instructional Units

Instructional Units	Physical and Social Parameters Developed
Movin' Magic	Body and spatial awareness, locomotor and non-locomotor skills, gross motor coordination, directionality, laterality, levels, pathways, rates of movement, body identification, creativity, problem-solving
Let's Play!	Independent movement choice, locomotor skills, spatial awareness, small and large object manipulation, hand-eye and foot-eye coordination, throwing, accuracy, agility, fleeing, chasing
Beanbag Bonanza	Small object manipulation, hand-eye coordination, tracking, fine motor control, grasping, tossing, catching, accuracy
Hoop Hoopla	Large object manipulation, gross motor coordination, body and spatial awareness, tracking, balance, rhythm
Perpetual Parachute	Group cooperation, listening skills, general coordination, locomotor and non-locomotor skills, strength, creative movement
Kiddie Stunts	Gross motor coordination, body and kinesthetic awareness, balance, strength, creative movement
Up, Up and Away	Hand-eye coordination, tracking, fine and gross motor coordination, striking skills
Rowdy Ropes	Balance, rhythm, strength, endurance, problem solving, creativity
Hold It! Catch It!	Small and large object manipulation, hand-eye coordination, tracking, dribbling, tossing, catching, throwing, accuracy
Silly Scarves & Streamers	Hand-eye coordination, tracking, gross motor coordination, rhythm, creativity, self-expression
Fancy Feet	Foot-eye coordination, gross motor coordination, striking skills
Dynamic Duo	Cooperative skill development, hand-eye coordination, tracking, small object manipulation, fine motor control, grasping, tossing, catching, accuracy

helps with warming up all parts of the body or helps to focus children for kinesthetic integration of movement and music. The goal was to keep the children engaged in physical activity as much as possible during their movement time. The main activity of the lesson focused on the introduction of basic motor skill development and acquisition, particularly as it relates to the development of body/limb/object coordination and specialized movement skills (e.g., object manipulation, dance, striking, etc.). Specialized units were designed to introduce children to a variety of manipulative and stimulating environments that were organized into progressive units. During both the Good Vibrations and main lesson segments, children were presented with opportunities to develop social and personal skills through positive interactions. The enhancement of a child's self-perception and self-image was an integral part of the physical activity class. Approximately 75% of the main lesson was devoted to moderate-vigorous physical activity.

Daily lesson plans were provided for each instructional unit. There were 10 lessons in each of the 12 instructional units. There were seven compact discs containing three-minute activity songs that were incorporated into each instructional unit as a catalyst to facilitate movement. These were designed to provide a progression in motor development and main lesson activities. Many units began with "Exploration Time" by providing a time for children to "just play" with an item, which stimulated many processes to begin immediately inside the brain. "Exploration Time" prepared a child for upcoming activity and generated focus; encouraged problem-solving, and creativity; provided a warm-up for more vigorous activity to come; and, was used if attention span waned during activity session. Immediately following exploration was a "Challenge" section. Here the teacher/aide provided specific prompts for the children to try. In this section the teacher/aide provided direct instruction as well as guided instruction. Each unit concluded with closure; praising the children's participation and creativity. All of the intervention teachers/aides completed a lesson quality assessment form after completing each lesson.

Procedure for the Intervention

The intervention was five months with one additional month for baseline assessments and one additional month for post assessments. The four HA centers were matched by enrollment and randomly assigned to intervention or control and the children were assessed at baseline and at post-intervention. Five classrooms were randomly selected from each center (total n = 20; 10 intervention and 10 control). The average classroom size ranged from 11 to 19 children ($\bar{x}$ = 15.7 ± 2.6 children).

The 10 intervention teachers and 9 aides attended the SPARK-EC training. The aides assisted the teacher with each lesson and served as a back-up when the teacher was absent. The weekly intervention delivery plan included: three days per week the teacher and the aide were responsible for conducting the SPARK-EC lesson; and, one day a week the trained research staff conducted the lesson by themselves. The sequence in which the weekly lessons were delivered varied across the intervention classrooms. This flexibility in delivering the weekly lessons was necessary to accommodate daily routines and needs of the teachers and the small number of research staff hired to assist with the intervention.

Training for HS Teachers/Aides

SPARK staff provided one full day workshop for HS teachers/aides and research facilitators to present the SPARK-EC program. They provided curriculum (instructional units, daily lesson plans, and resource materials); and trained the staff to implement the SPARK-EC program. The goal of the SPARK-EC workshop was to provide strategies and tips to increase the quantity and quality of physical education/activity classes; and to promote the maintenance of physical activity away from class as part of a healthy lifestyle. The three primary factors that contributed to a successful staff development program were utilized. They were: 1) fostered teacher/aide awareness regarding the goals of SPARK-EC and how they may differ from current programs; 2) provided ongoing, skill-specific training; and, 3) solicited and encouraged group interaction, feedback, and support.

Overview of Measures

Test of Gross Motor Development – 2 (TGMD-2)

The instrument selected for the proposed research was the Test of Gross Motor Development – 2 (TGMD-2). Created and standardized by Dr. Dale Ulrich, it was a norm-referenced measure of common gross motor skills which has been proven to be valid and reliable for use with learners between the ages of 3 and 14 years [42]. TGMD-2 assesses 12 skills; 6 for locomotor and 6 for object control. Detailed descriptions and illustrations of the gross motor skills and a simplified scoring system allowed us to administer the TGMD-2 in 15-20

minutes. Reliability coefficients for the locomotor subset averaged .85, the object control subset averaged .88, and the gross motor composite averaged .91. Coefficient alphas for selected subgroups were all above .90 for the subtest and the composite. Time sampling reliability coefficients ranged from .84 to .96.

The TGMD-2 was administered to the preschool children as a regular part of their motor development curriculum by a team of well-trained evaluators at pre- and post-intervention. The TGMD-2 assessed fundamental movement skill proficiency. In the locomotor subtest, the children were assessed on the following: run, gallop, hop, leap, horizontal jump and slide. On the object control subtest, the children were assessed on the following: striking, stationary dribbling, catch, kick, overhand throw, and underhand roll [42]. The child was given two trials on each skill. A number of components for each skill were evaluated; a score of "1" indicated the student performed the skill component correctly and a score of "0" indicated that the student did not meet criteria. A raw score was computed for each skill; these scores were used to compute a subtest score for both the locomotor and the object control subtests. The raw subtest scores were converted to standard scores and it was possible to relate these scores to age equivalencies.

TGMD-2 training focused on the identification of individual skill components for each of the locomotor and object control skills. The training method consisted of detailed skill analysis, video demonstration with component breakdown, video practice evaluation and live practice evaluation. Upon completion of training, each evaluator was required to attain a reliability of at least 85% on all skills compared to a video evaluation standard. The TGMD-2 data was not collected on the same day when the accelerometer data were collected. The TGMD-2 data were collected periodically in the mornings at the centers. Data from the TGMD-2 was not used as part of the intervention.

Accelerometers

Actical (Respironics, Philips Home Health Care Solutions, Bend, OR), a uniaxial accelerometer, was used to monitor physical activity of the children while attending HS at baseline and post intervention. This compact, non-intrusive monitor (10 mm thick, 39 mm diameter, and 17 g total weight) is appropriate for preschool children. Actical is sensitive to movements in the 0.5 to 3 Hz range. Actical sums 32 values in a 1-second window, divides the sum by four, and then adds this result to the accumulated value for the epoch. The Actical was affixed side by side above the iliac crest of the right hip with an adjustable elastic belt. Epochs were set so that data was collected every 15 seconds which was the suggested time interval to be used with young children [17]. Thresholds for sedentary/light and light/moderate-vigorous physical activity levels determined by room calorimetry in 64 pre-schoolers were applied to classify the accelerometer data [20].

Children in the intervention group and the control group wore the monitors throughout the entire HS day. All children were given the opportunity to habituate prior to data collection to the activity monitor so that period measurements would reflect "activity" and not simply a fascination with the monitor. Each child was introduced to the monitors at the HS centers one day prior to the two days of actual data collection. Research staff documented the nap time for each day at the center during the assessment period. Data collected from the accelerometers was used to assess changes in physical activity patterns in the HS center only. The intervention and the control centers were not assessed on the same day.

Anthropometrics

A portable stadiometer was used to measure height to the nearest cm, and an electronic scale to measure weight to the nearest 0.1 kg [43]. The children were asked to remove shoes, and heavy outer clothing such as a coat or bulky sweater. The children were also asked to remove hats, hair barrettes or anything else in their hair, which could prevent obtaining an accurate measurement of height at the crown of the head. Duplicate measures were taken of weight and height with the average recorded as the value. A third measurement was taken if there was > 0.2 cm or 0.2 kg difference between the two; median values were used when 3 measurements were taken. BMI was calculated as weight in kilograms divided by height in square meters. BMI Z scores were calculated for each child based on the 2000 Center for Disease Control (CDC) growth charts [44, 45]. A BMI in excess of 85th percentile was used to define overweight and > 95th percentile as obese in children [46]. Change in BMI was not our primary outcome. However, we did look at changes in BMI and used BMI as a covariate in the analyses.

Process Evaluations

Process evaluation enabled us to ensure that the program was being delivered according to protocol.

Process evaluation fulfilled 3 functions during the intervention: a) to describe program implementation (e.g., program dose, program content), b) to provide information for quality control and monitoring, and c) to help explain program effects [47-49] .

Process data was obtained through observations of SPARK-EC lessons using two measures that were used in the multi-site study CATCH, [50-55] SPARK, [32] and other NHLBI-funded programs [56]. The System for Observing Fitness Instruction Time (SOFIT) was a validated [57] comprehensive system to measure 1) observed lesson length, 2) number of lesson minutes children were engaged in each of five activity levels and MVPA, 3) lesson content, and 4) teachers promotion of physical activity during SPARK-EC activity lessons. Assessment staff completed classroom training, videotape analysis, and field practice and certification assessments. Accuracy was measured periodically through the coding of pre-coded "gold standard" videotapes. In the field, 10% of SPARK-EC activity lessons were coded simultaneously by two independent observers. Immediately after observing an entire activity lesson using the SOFIT instrument, a Physical Education Observation and Dosage Form (PEODF) [52] was completed. This measure assessed whether the children received prompts or encouragement to be physically active from the teacher during the activities lesson; included instructional prompts for skill topography; children received praise for their active participation; children appeared to enjoy themselves; clear instructions were given; and, activity lesson had adequate student: equipment ratio. In addition, the number of minutes of activity provided to the class today and the four most recent school days (obtained from the teacher) were recorded.

Procedure for Assessments

All children in the 20 randomly selected classrooms were assessed at pre- and at post-intervention. Physical activity patterns for two days were assessed on 272 children. The TGMD-2 was collected on 264 children in the 20 randomly selected classrooms at baseline and at post intervention in a station-based approach. It took one-half hour to assess a group of four children by one evaluator. Heights and weights were collected on 283 children. The assessment of physical activity and TGMD-2 were staggered. The assessments were conducted by trained assessment research staff that were blinded to the intervention. A separate research team conducted the intervention and completed the process evaluations.

One month prior to the intervention, baseline assessments were collected five days a week in both of the intervention centers. One intervention team conducted the TGMD assessments and another team collected the accelerometer, height and weight data. Once the baseline data was collected at the two intervention centers, the assessment teams collected the baseline data at the control centers which took an additional month. For follow-up, assessments were conducted at the control centers during the five month intervention and an additional month was needed to complete post-assessments in the intervention centers.

Statistical Analysis

Power and Sample Estimation

As we had multiple outcomes, BMI-for-age Z-score, TGMD, and percent time spent in the physical activity levels in the study, a power analysis for the primary outcome variables with the nested two-group randomized design, and repeated observations (baseline and follow-up) showed that given the sample size of 132 preschool children provided 80 percent power at the .05 level of significance to detect a main effect of size .16 in units of standard deviation. An intra-class correlation (ICC) of 0.02 [58] was used to calculate variance inflation to account for design effect, thus yielding a sample size of 213. Adjusting for an average attrition rate of 25%, 268 students were to be recruited, 67 subjects per school. However, given the number of children varies within the classrooms, all of the children in the participating classrooms were recruited to participate. Thus, a total sample of 295 children participated at baseline across the four HS centers.

Data Analyses

Descriptive analyses was performed to compare baseline age, race/ethnicity, weight, height, Actical, and TGMD by gender to examine if there was a significant difference in characteristics between control and intervention groups. To account for clustering effects and provide greater efficiency because the children were nested within classrooms and nested within centers, we performed multi-level modeling, called hierarchical linear models or linear mixed models. We also used the standard residual plots to assess normality or linearity. Moreover, analyses with Actical outcomes were stratified by gender because the interaction between gender and intervention was significant (P-interaction >0.1). The effect size (ES) was calculated using Cohen's d coefficient to evaluate

the intervention effect on the outcomes. Effect sizes of 0.2 are considered small, 0.5–0.6 are considered medium, and > 0.80 are considered large [65, 66]. Statistical analyses were performed using Stata (version 11.1, Stata Inc., TX, USA) or the Statistical Analysis Software.

RESULTS

Physical Education Observation and Dosage Form (PEODF)

The intervention was five months in duration and included two centers and five classrooms per center. The activities were delivered by ten teachers, nine aides, and three research staff facilitators. There were 12 activities with an additional activity being, "Teachers Choice". An activity was conducted 92% of the time, four days a week, during the five month intervention. A total of 490 activities were conducted; equally distributed across both of the intervention centers. Twenty-four percent of the activities were conducted by the research staff with the remaining 76% conducted by the teachers/aides. It took approximately four minutes to prepare the children for the activity. The average length of one activity was 17 minutes. Average class size participating in the activities was 16 children per classroom, with an average of two children absent. More than 50% of the class was active during the lesson time and more than 50% of the children appeared to enjoy the activity. On average, the total activity was completed with no changes to the protocol and with no interruptions. On average, the activities included both a warm-up and cool-down. The students were encouraged to be physically active most of the time and they received praise for their active participation. The lessons had adequate student-equipment ratio and the group sizes were appropriate for the activities. Teachers showed enthusiasm for teaching.

System for Observing Fitness Instruction Time (SOFIT)

Overall, children engaged in 4.9 minutes of walking and 10.0 minutes of standing, sitting, or lying down, 1.8 very active minutes, and 6.6 minutes of moderate-vigorous physical activity. Each SPARK-EC lesson included 5.9 minutes of game play, 4.2 minutes of class management, 2.3 minutes of general knowledge, 3.9 minutes of skill drills, and, only 0.6 minutes of fitness activity.

Pilot Study

At baseline, the mean age of the HA preschoolers was 4.3 years, and about 40% of them were overweight or obese. There were no differences in the baseline age and weight status between intervention and control groups (Table **2**).

Table **3** shows the descriptive statistics of physical activity, gross motor skills, BMI, weight, and height in intervention and control groups at baseline and follow-up, stratified by gender. During baselines' awake time, the average time children spent in sedentary physical activity was 51% and light physical activity was 43%. The means of TGMD quotient and percentile rank for boys were 86 and 23, respectively, while girls quotient and percentile were 82 and 16, respectively. In the follow-up survey, during the awake time, the average time children spent in sedentary physical activity was 45% and light physical activity was 44%. Boys' TGMD quotient and percentile rank were similar to girls.

We did not observe a statistically significant difference between intervention and control groups in

Table 2: Subject Characteristics[1]

	Boys		Girls	
	Control (n=76)	Intervention (n=84)	Control (n=68)	Intervention (n=67)
	Mean (SD)[1]	Mean (SD)	Mean (SD)	Mean (SD)
Age (year)	4.3 (0.6)	4.3 (0.6)	4.3 (0.8)	4.2 (0.7)
BMI-for-age Z-score	0.8 (1.2)	0.7 (1.5)	0.6 (1.1)	0.8 (1.3)
Weight Status (n (%))[2]				
Normal weight	43 (58.9)	46 (55.4)	40 (62.5)	37 (58.7)
Overweight	16 (21.9)	16 (19.3)	16 (25)	9 (14.3)
Obese	4 (19.2)	21 (25.3)	8 (12.5)	17 (27.0)

[1]Sample size: demographic information: n=295; BMI: n=283; Mean (SD)=Mean (Standard Deviation).
[2]The weight status was defined by using the age- and gender-specific CDC BMI growth charts.

Table 3: Mean (95% Confident Interval) for Physical Activity Level in HS, TGMD, Weight and Height Status[1,2]

	Boys				Girls			
	Baseline		Follow-up		Baseline		Follow-up	
	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention
BMI-for-age Z-score	0.7 (0.5, 1.0)	0.7 (0.3, 1.1)	0.8 (0.5, 1.1)	0.6 (0.2, 0.9)	0.6 (0.3, 0.8)	0.8 (0.4, 1.1)	0.69 (0.4, 1.0)	0.6 (0.3, 1.0)
TGMD[4]								
Quotient	86.7 (83.7, 89.6)	86.1 (83.6, 88.6)	87.9 (85.0, 90.7)	85.2 (83.1, 87.4)	82.4 (80.1, 84.7)	81.9 (79.1, 84.7)	79.9 (76.8, 83.0)	81.2 (78.6, 83.8)
Percentile rank	24.6 (19.9, 29.3)	23.0 (17.3, 26.7)	25.9 (21.1, 30.8)	19.6 (15.9, 23.3)	15.4 (12.2, 18.6)	15.8 (11.9, 19.7)	13.8 (9.8, 17.8)	14.0 (10.2, 17.8)
Physical activity level during awake time[3]								
Total awake time (min)	280 (276, 285)	281 (275, 288)	280 (276, 285)	254 (248, 260)	283 (276, 290)	282 (274, 289)	277 (272, 282)	257 (252, 262)
Sedentary (min)	141 (133, 149)	146 (138, 155)	135 (125, 145)	152 (143, 162)	129 (121, 137)	116 (108, 124)	125 (116, 134)	130 (121, 140)
Sedentary (%)	50.7 (47.9, 53.6)	52.8 (49.6, 56.0)	45.6 (42.7, 48.4)	46.2 (43.0, 49.5)	47.0 (43.5, 50.5)	53.5 (50.0, 56.9)	45.4 (42.0, 48.9)	50.6 (46.7, 54.4)
Light (min)	122 (115, 130)	114 (105, 123)	127 (118, 136)	112 (104, 121)	127 (120, 133)	115 (108, 121)	130 (121, 139)	109 (101, 116)
Light (%)	43.1 (40.7, 45.4)	40.6 (37.9, 43.3)	45.5 (43.2, 47.7)	44.7 (42.1, 47.3)	45.9 (43.0, 48.9)	40.4 (37.5, 43.4)	45.9 (43.1, 48.7)	42.2 (39.2, 45.3)
Moderate-vigorous (min)	18.0 (15.6, 20.4)	18.3 (16.2, 20.4)	19.2 (16.8, 21.7)	16.5 (14.1, 18.9)	24.8 (21.7, 27.9)	22.9 (20.0, 25.7)	24.0 (20.9, 27.2)	18.0 (15.3, 20.7)
Moderate-vigorous (%)	6.2 (5.6, 7.2)	6.6 (5.8, 7.2)	8.8 (7.7, 9.9)	9.0 (7.9, 10.1)	6.9 (6.0, 7.8)	5.8 (5.0, 6.7)	8.5 (7.5, 9.6)	7.0 (5.9, 8.0

Abbreviation: BMI: Body Mass Index; TGMD: Test of Gross Motor Development; LMVPA: Light -Moderate –Vigorous.
[1]Mean (95% Confident Interval).
[2]Sample size: anthropometric indices: n=283; Actical: n=272; TGMD: n=264.
[3]Actical categories were defined based thresholds developed by Adolph *et al*. (2011)).
[4]The TGMD-2 was used to define the TGMD quotient and percentile rank.
[5]Z-score for anthropometric indices were defined by using the age- and gender-specific CDC growth Charts.

physical activity level during the awake time, TGMD or weight status. Both groups showed a non-significant increase in moderate-to-vigorous physical activity levels (2.5% in boys and 1% in girls). TGMD quotient and percentile rank appeared to be weaker. There was no change in weight- and BMI-for-age Z-scores (Table **3**).

Table **4** shows results from mixed effect models with nested effect by classroom and center. The intervention did not result in a significant change in BMI-for-age Z-score in both crude and gender-race-adjusted models; effect size (ES) was small (ES=0.01). Children in the intervention group did not have an increase in TGMD quotient or TGMD percentile rank. The effect size of quotient (ES=0.14) and percentile rank (ES=0.19) were small. In boys, intervention did not affect physical activity levels (variation from 0–2 percentage points). In girls, intervention was associated with about six percentage points higher in sedentary activities during the awake time ($p<0.01$) with a medium effect size (ES=0.44).

DISCUSSION

When designing PA interventions it is important to keep in mind the developmental stage of preschool children. Preschoolers lack the attention span and physical and motor development for continuous bouts of high intensity PA. The goal of this study was to implement and a PA change intervention targeted at HS preschool children. The physical activity program

Table 4: Effect of Intervention to Each Individual Outcome Using Mixed Effect Models[1]

Outcomes	Estimate (se)	95% CI	ES	P-value
BMI-for-age Z-score[2]	-0.0 (0.2)	(-0.3,0.3)	0.01	0.957
TGMD[3]				
Quotient	-1.7 (1.6)	(-5.0,1.6)	0.14	0.325
Percentile rank	-3.6 (2.6)	(-8.9,1.7)	0.19	0.184

Physical Activity (Actical)	Boys				Girls			
	Estimate (se)	95% CI	ES	P-value	Estimate (se)	95% CI	ES	P-value
Sedentary (minutes)[4]	2.5 (6.6)	(-10.5, 15.4)	0.07	0.707	15.3 (6.6)	(2.2, 28.4)	0.44	0.022
Sedentary (% of minutes)[5]	1.7 (2.3)	(-2.9,6.2)		0.474	5.9 (2.3)	(1.4,10.4)		0.011
Light (minutes)	-2.4 (4.9)	(-12.2, 7.4)	0.08	0.625	-12.1 (5.2)	(-22.4, -1.9)	0.45	0.020
Light (% of minutes)	-1.7 (1.8)	(-5.1,1.8)		0.344	-4.7 (1.8)	(-8.2,-1.2)		0.009
Moderate-Vigorous (minutes)	0.1 (1.9)	(-3.8, 3.9)	0.00	0.977	2.9 (2.2)	(-7.5, 1.5)	0.25	0.189
Moderate to Vigorous (% of minutes)	0.0 (0.7)	(-1.3,1.4)		0.946	-1.1 (0.1)	(-2.6,0.5)		0.166

Abbreviation: BMI: Body Mass Index; TGMD: Test of Gross Motor Development; LMVPA: Light-Moderate-Vigorous; Estimate (se): Estimate (standard error);ES: Effect Size of intervention.

[1]Coefficient for Intervention from Multilevel mixed-effect models, which took into account within and between individual variations and the nesting effect of intervention by classroom.

[2]Adjusted for gender.

[3]Adjusted for gender, age, and BMI z-score.

[4]The analyses were stratified by gender, controlling for age and total awake time (minutes) per day.

[5]The analyses were stratified by gender, and adjusted for age.

focused primarily on the development of gross motor skills. Children need to develop gross motor skills before they can engage in daily MVPA [59]. Thus, the CIA program was designed to improve gross motor skills of preschool children which would better prepare them to increase their physical activity. The two primary hypotheses that were tested included: 1) children who received the CIA program would demonstrate increased physical activity compared to children in the control group and, 2) children who received the CIA program would demonstrate increased gross motor skills compared to children in the control group.

This pilot study did not result in statistically significant differences between intervention and control groups in physical activity level during awake time in HS, total gross motor development, or weight status. There are several possible explanations for showing non-significant results in the targeted outcomes. The intervention provided 15-20 minutes per day for four days/week of structured physical activities which might have been an inadequate dose to have a net effect on children's' physical activity while at HS. Furthermore, as planned the intervention replaced unstructured recess play in the HS daily schedule, even though one study found that increasing preschoolers' outdoor free playtime did not increase their physical activity levels [60]. Data from our study suggests that substituting a program to increase gross motor skills may not be sufficient to increase physical activity in the short term. Moreover, a more comprehensive intervention may be needed that includes the CIA intervention to improve gross motor skills, in addition to increasing outdoor playtime and providing activity-friendly equipment to the outdoor preschool playground [61]. We cannot rule out the possibility that the lack of differences resulted from insufficient power due to the relatively small sample size and short duration of this feasibility study. However, we did demonstrate that it was feasible to conduct the SPARK-EC curriculum. Process evaluation data showed that there was adherence to protocols

and the intervention was delivered 92% of the time, four times per week, during the five month intervention.

The intent of the NIH R21 funding mechanism is to conduct pilot studies to develop and conduct the study procedures for new interventions and to provide "proof of concept" [62]. Commonly, a pilot study is a "small-scale test of the methods and procedures to be used on a larger scale…" [63-66]. Results from this pilot study will be used to support a more expensive and lengthier efficacy or effectiveness study. Thus, it is important that one understands the limitations in the interpretation of pilot studies [63-66].

Several systematic reviews of interventions for the prevention of overweight and obesity in preschool children have been published [67-69]. Only two interventions [70, 71] were carried out in preschool settings with an exclusive physical activity component, both of which showed no significant differences in PA and BMI in children in the intervention and control groups. However, authors of one of the studies [67, 71] emphasized the importance of developing a sustainable intervention (low cost, easily implemented, well accepted by day care staff and children) for increasing PA and improving basic motor skills. Other studies included multi-component interventions for preschool children, focusing on both diet and PA within the day care center and in the family environment [67-69, 72-77]. These multi-component programs appear to be a more promising approach for increasing PA of preschoolers. However, the efficacy, effectiveness, generalizability, and sustainability of well-planned preventive PA programs with young children need to take into consideration some of the contextual and social factors associated with preschoolers PA behaviors [78-82].

CONCLUSION

In summary, we demonstrated that it is feasible to conduct the SPARK-EC curriculum among HA preschool children attending HS centers but that an increased dose and/or longer intervention duration will be required to impact gross motor skills, weight status and physical activity levels during this critical early childhood development stage.

ABBREVIATION

CIA = Children in Action

TGMD = Test of Gross Motor Development

SPARK-EC = Sports, Play, and Active Recreation for Kids-Early Childhood

U.S. = United States

HS = Head Start

NHANES = National Health and Nutrition Examination Survey

BMI = Body Mass Index

MVPA = moderate-to-vigorous physical activity

HA = Hispanic-American

CATCH = Coordinated Approach to Child Health

NHLBI = National Heart, Lung and Blood Institute

SOFIT = system for observing fitness instruction time

PEODF = Physical Education Observation and Dosage Form

NIH = National Institute of Health

PA = Physical Activity

ES = Effect Size

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