

Protocol Title: Painting Preschool Playgrounds: a scalable approach to increasing physical activity and motor skills in Louisiana preschool aged children. Aim 1: Observation

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Objectives

A. Specific Aims

Preschool is a critical period during which children develop fundamental motor skills, build confidence in their movement, and start a physical activity trajectory that follows through adolescence and beyond. Unfortunately, few sustainable interventions have succeeded in increasing preschool children’s physical activity, and subsequently children are developing obesity at alarming rates.¹ A simple, low-cost strategy is the addition of colorful markings (i.e. hopscotch, foursquare, fun trails) to existing playgrounds or open spaces. These “painted playgrounds” have been shown to be effective to increase physical activity in older school-aged children but remain understudied in preschool children.^{1,2,3} The proposed project will implement and test the effectiveness of a scalable playground stenciling intervention to increase physical activity and fundamental motor skills and decrease sedentary behaviors among preschool aged children attending childcare centers.

The aim of this pilot project is:

Aim 1: To examine the physical activity environment of licensed childcare centers before and after the implementation of a promising (cost-effective, easily scalable) playground stenciling intervention.

The aim will be achieved through a prospective observational epidemiological approach before and after a stenciling intervention is implemented. Among 4 childcare centers licensed in East Baton Rouge Parish (EBR), we will first observe the playground environment to assess the equipment, space, ground material, etc. to provide a baseline measure of the physical activity environment prior to stenciling and ensure that intervention and control centers have similar playground environments. We will use a modified behavioral observation method, the System for Observing Play and Leisure Activity in Youth (SOPLAY), during recess to identify changes in physical activity after the stencils are added and which stencils are generating the biggest changes in physical activity. We will also administer surveys to center directors to further understand the physical activity environment (i.e. policies, additional PA support, etc.) in each center.

This project will test the effectiveness of a promising (cost-effective, easily scalable) playground stenciling intervention in order to validate the need for dissemination to numerous childcare centers across Louisiana. Ultimately, this pilot may launch an innovative strategy that has the potential to disrupt negative trends in obesity and sedentary behavior among Louisiana preschoolers.

B. Background

The significance of this project stems from Louisiana’s prevalence of preschool obesity which is 60% higher than the national average: 13.8% of preschoolers in the state are obese compared to 8.4% nationally.^{4,5} Physical activity during early childhood is known to reduce the risk of being overweight or

obese and therefore protect against the development of comorbidities, such as heart disease, diabetes, etc. later in life.⁶ Furthermore, at this young age the development of fundamental motor skills is highly related to physical activity and is therefore an important correlate to obesity.⁷ Despite assumptions that young children are active throughout the day, studies indicate that almost half of preschool play time is spent in sedentary activities.¹ Over 80% of children spend some time in childcare settings by the age of 3 years, making childcare facilities an important venue for the promotion of fundamental motor skills and physical activity.⁸ As playground stenciling has been shown to increase moderate to vigorous physical activity (MVPA) during recess among older children, it is necessary to determine whether it has the same benefit for preschool aged children. Therefore, we propose to use a scientifically rigorous design (intervention vs. wait-list control) to determine the effectiveness of playground stenciling in Louisiana preschool aged children, a population burdened with an urgent, established obesity epidemic.

Inclusion/Exclusion Criteria

Four licensed (two intervention and two wait-list control centers) DOE Class A or B childcare centers will be selected from a list of all DOE licensed childcare centers in EBR.

Inclusion Criteria:

- Licensed by DOE as a Class A or Class B childcare center
- Current childcare enrollment of at least 20 children between the ages of 3-6 years
- Has a playground/play area with adequate space for stenciling

Exclusion Criteria:

- Childcare center and/or childcare center director are unwilling to participate.

Number of Subjects and Subject Timeline

We plan to evaluate 4 EBR licensed DOE Class A or B childcare centers over a 6 month period. Each childcare center will participate in the study for approximately 2-3 months, including prospective observational evaluations of the childcare center playground environment. We plan to conduct all center evaluations between September 2017 and December 2017.

Study Timeline

This project will occur from July 1, 2017, to July 1, 2018. We will recruit, implement and evaluate playground stenciling in 4 East Baton Rouge licensed childcare centers from July 1, 2017, to December 1, 2017. The data analysis, manuscript and toolkit development, and application for additional funding to facilitate expansion to numerous childcare centers across Louisiana will occur from December 1, 2017, to July 1, 2018. Furthermore, during December 2017 we will provide stenciling on the playground to the wait-list control childcare centers so that children who attend the control centers will receive the same benefits from participating in this pilot study as those children at the intervention centers. A detailed timeline of the implementation procedures for the stenciling intervention and evaluation is displayed in a table below. The recruitment of the four childcare centers will take approximately 9 weeks. During this time project staff will assess the playgrounds at childcare centers to ensure that our intervention and wait-list control schools have similar playground environments and that it is feasible to provide playground stenciling at all centers. Project staff will obtain consent from the childcare center directors in the form of a permission letter signed by the director. The playground at the intervention centers will then be painted using the stencils.

Table 1: Study Timeline																		
	Weeks																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Recruitment/ Planning	█	█	█	█	█	█	█	█	█									
Playground assessment				█	█	█	█	█										
Pre-Testing									█									
Stenciling										█	█							
Novel-effect Wait Period												█	█	█	█	█	█	
Post-Testing																		█

Recruitment Methods

Childcare Centers:

Four childcare centers will be invited to participate. Childcare centers may be contacted via phone, mail, email, and/or in-person. Once interest is expressed by the childcare center’s director/administration, PBRC staff will travel to the childcare center to examine their playground/outdoor space. Once the playground/outdoor space is deemed valid for the study, written documentation will be obtained from the childcare center’s director/administrator to allow the conduct of study procedures at that site. If a center is not interested in participating or their playground does not meet study criteria, another childcare center will be randomly selected. This process will continue until 4 childcare centers have been successfully enrolled. There are currently 192 licensed childcare centers totaling an approximate capacity of 16,500 students and 13 Head Start centers in EBR, so we do not envision problems recruiting 4 childcare centers for evaluation. We aim to recruit all 4 childcare centers between July 2017 and September 2017.

Consent Process

Written approval from the childcare center’s director/administrator to allow the conduct of playground observations, the implementation of the intervention (playground stenciling), behavioral observation pre and post intervention and director-completed surveys will serve as one formal consent document.

Parents will be notified about the study prior to data collection, including information about the study purpose, procedures, and timeline. Parents will be notified about the study in at least 2 of the following ways: informational handout/flyer, phone call, email, mail, or in-person, and will be given adequate time to refuse for their child to be observed. All children in the selected classroom will be included in the recess observations except for children whose parents explicitly request for their child to be excluded from the observations. These children will be relocated to another play area or otherwise excluded from observational counts during the observation period. Children and teachers will be notified that researchers will be present during recess but the full purpose of the study will not be disclosed to children or teachers at the childcare center until after the completion of all recess observations, so as not to alter the children’s behaviors or teachers’ behaviors.

Procedures

Below are the procedures that will be completed during study participation (Table 2).

Table 2: Procedures and Timeframes				
	Baseline Intervention Center	Baseline Control Center	Follow-up Intervention Center	Follow-up Control Center
Childcare Center Director’s Survey	X	X	X	X
SOPLAY (Observation)			X	X

Childcare center policies and practices surveys. Surveys will be administered to the director of each childcare center to determine the following: amount of time allowed for free play and amount of time spent outside (including exact outdoor play times for the week of evaluation); staff support for physical activity, structured programs and/or field trips that allow children to be physically active (including number of times per day or week); if one or more community organizations support or provide physical activity programs at the center; and whether or not the childcare center has policies regarding television viewing and computer use.

SOPLAY. We will use an adapted version of the System for Observing Play and Leisure Activity in Youth (SOPLAY) tool, which was created to objectively evaluate physical activity and energy expenditure in a targeted area.¹² The physical activity coding scheme used in SOPLAY has been found to be valid in relation to heart rate monitor measurements. SOPLAY also displays adequate inter-observer reliability (IOA=80%; R=.75). A research assistant will be trained to implement SOPLAY and will attend two trial observations prior to observing recess for this pilot study. A research assistant will conduct two observations during recess hours of the outdoor physical activity environment of both childcare centers after the stenciling intervention has been implemented. During the observation recesses, a trained data collector will observe all activities of the playground at the intervention childcare center, including activity intensity, environment characteristics, equipment availability/ accessibility, organized activities, supervision, and child characteristics.

Primary Endpoints and Data Analysis Plan

Primary endpoints include change in overall SOPLAY score and change in all SOPLAY subscales. Statistical analyses will be performed with the latest version of SAS. Means, standard deviations, and Pearson correlations will be calculated to describe the sample and examine differences between the intervention and control group. Differences in center characteristics (i.e. racial distribution) will be tested using t-tests and chi-square tests.

Data Management and Confidentiality

The Pediatric Obesity and Health Behavior Laboratory, supervised by Dr. Staiano, will have primary responsibility for data collection, data management, manual data entry, and data analysis. All electronic data will be stored in the secure Pennington database, with access given to only necessary, HIPAA-

certified staff. All hard copies of data will be stored in a secure, locked cabinet at Pennington Biomedical Research Center. Data collected at the childcare centers will be securely transported to PBRC by trained staff. Access to data files can be made only with permission of the Principal Investigator. Data will be stored for 5 years following study completion.

Provisions to Protect the Privacy Interests of Subjects and Monitor the Data to Ensure the Safety of Subjects

This study does not involve more than minimal risk to participants. All data will be collected through non-invasive measurements, observations or surveys. All observations will take place during normal recess time and will be done as unobtrusively as possible. Observations will take place at the center level and thus will not include any personal identifying information of the children being observed. Survey items do not contain sensitive items to ensure childcare directors are comfortable responding. The parent and/or pertinent childcare personnel will be notified of any significant health problems that are brought to our attention and participants will be referred to the participant's usual source of medical care.

Withdrawal of Subjects

Participation is voluntary, so childcare centers or the child may withdraw from the study at any time. Data that have already been collected during the course of study participation from a withdrawn childcare center will be used, unless a specific request is otherwise received. Childcare centers may be withdrawn from the study for the following reasons:

- Unwillingness on behalf of the childcare center to participate in the study or cooperate with study staff

Risks/Benefits to Subjects

There are no foreseeable risks to participants in this study. We cannot promise any direct benefits to the participant, although the stencils may provide additional opportunities for physical activity and fundamental motor skill development.

Vulnerable Populations

This study will involve young children as participants (3-6 year olds). As such the children's parents/legal guardians will provide written informed consent. Furthermore, the childcare director will provide written permission for recess observations and the implementation of playground stencils.

Sharing of Results with Subjects

Study results will not be shared with participants unless requested. If requested, only group summary data will be available.

Setting

All childcare evaluations and study procedures involving children will be conducted in the East Baton Rouge community, at selected DOE licensed Class A or B childcare centers. Each childcare center will be required to provide written documentation to allow the conduct of study procedures at that site.

Resources Available

Amanda E. Staiano, Ph.D., M.P.P., *Principal Investigator*, is Assistant Professor and Director of the Pediatric Obesity and Health Behavior Laboratory at Pennington Biomedical. Dr. Staiano is a

developmental psychologist with expertise in epidemiological surveys of children's physical activity and screen-time and interventions to improve children's physical health.

Maura Kepper, Ph.D, Co-Investigator, is a postdoctoral researcher at Pennington Biomedical. Dr. Kepper is a trained behavioral scientist with expertise in physical activity assessments, surveys and observational assessments of children's behaviors and environments related to children's health.

Prior Approvals

The director/administrator of each childcare center will be required to provide written approval to allow the conduct of study procedures at their site.

Compensation for Research-Related Injury

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) will be available for this research study. In the event of injury or medical illness resulting from the research procedures, participants will be referred to a treatment facility.

Economic Burden to Subjects and Compensation

All visits will take place at the childcare center during normal hours and will not add any economic burden on the children being observed or childcare directors. Thus, no additional compensation will be provided to childcare centers, childcare directors, parents, or children participating in the childcare center evaluations.

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