Study Title: Painted Playgrounds: Aim 2: Assessments
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Protocol Title: Painted Playgrounds: a scalable approach to increasing physical activity and motor skills in Louisiana preschool aged children. Aim 2: Assessments

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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 test the effectiveness of a promising (cost-effective, easily scalable) playground stenciling intervention to increase physical activity, improve fundamental motor skills, and decrease sedentary behaviors of preschool aged children attending childcare facilities.

The aim will be achieved through a pilot project that is grounded in rigorous and reproducible methodology, meaning the results can be generalized to other parts of the state and held as a model throughout the country. We expect that children who attend the childcare center that receives the stenciling will have greater increases in moderate to vigorous physical activity (MVPA) and fundamental motor skill competency, and larger decreases in sedentary behavior, compared to children who attend the control facility (who will receive the stencils after an approximate 6 to 8-week delay). The main outcome variable will be percentage of recess time spent in MVPA, measured objectively using a physical activity monitor (i.e. accelerometer). Additional outcome variables include fundamental motor skill competency, measured using the validated Test of Gross Motor Development (TGMD-3; Ulrich, 2016), and the percentage of recess spent being sedentary (accelerometry). Parents will provide demographics of all consented children, and height and weight will be collected before and after the intervention. We do not expect changes in weight status during this short time period but will include obesity as a covariate to control for differences in MVPA that may be due to weight.

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

Inclusion Criteria:

- A child who attends a childcare center enrolled to Aim 1.
- A child who is ≥ 3 years and ≤ 6 years old

Exclusion Criteria:

- Parent/legal guardian is unwilling to provide written informed consent

Number of Subjects and Subject Timeline

We plan to enroll up to 72 children. Each child will participate in the study for approximately 8 weeks. Surveys take parents about 20-30 minutes to complete. Anthropometric measures (height and weight) take about 5-10 minutes for each child to complete and will be performed at baseline and post-intervention (6-8 weeks follow-up). Fundamental motor skill competency testing will be performed at baseline and post-intervention (6-8 weeks follow-up) and will take approximately 30 minutes per child. Additionally, cognitive testing takes approximately 30 minutes for each child and will be performed at follow-up only. The child will be given an ActiGraph accelerometer to wear for 7 days at both baseline and post-intervention (6-8 week follow-up). An ActivPal accelerometer will also be distributed for the child to wear for 4 days at follow-up only. We plan to conduct all child visits between September 2018 and May 2018.

Study Timeline

This project will occur from July 1, 2017, to July 1, 2019.

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																		
Pre-Testing																		
Stenciling																		
Novel-effect Wait Period																		
Post-Testing																		

Recruitment Methods

All parents of children between the ages of 3-6 years at the 4 selected childcare centers will receive an informational handout/flyer and consent form to participate in study procedures. Informational materials about the study may also be distributed to parents via email, mail, fax, phone, or in-person through the school. Children for whom a completed consent form is returned by their parent or legal guardian will be eligible to participate. We aim to recruit up to 72 children (18 per center) between August 2018 and February 2019.

Consent Process

Parents/guardians will provide written consent for their child to participate in the study prior to data collection. The consent will include information about the study purpose, procedures, and timeline. Consent forms will be sent home with children and returned by parents to the childcare center staff. All children whose parents do not complete a written consent form within the given time will not be included in the study. Due to their young age, children will not provide formal assent, but will be notified that researchers will be present in the classroom. The full purpose of the study will not be disclosed to children at the childcare center until after the completion of all measurements and observations, so as to minimize the alteration of the children's 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
Consent	X	X		
Parent Survey	X	X		
Height	X	X	X	X

Weight	X	X	X	X
TGMD-3 (Motor Skills)	X	X	X	X
Actigraph (Physical Activity)	X	X	X	X
Ages and Stages (Motor Skills Questionnaires – 4 yr olds only)			X	X
activPAL (Physical Activity – 4 yr olds only)			X	X
Card Sort, Go/No-Go, Mr Ant (Cognitive/Executive Function Tests – 4 yr olds only)			X	X

Parent survey. Parents will be asked to complete a questionnaire that will provide information on the child's sociodemographic characteristics, including sex, date of birth, and parents' marital status, highest level of education, family income, occupation, employment status, and the child's physical activity, sedentary time, screen time and sleep time. There are also questions pertaining to electronic screen device use by the parent/caregiver with the child. The final sections asks about the child's sedentary travel time and time spent outside. The poverty guidelines developed by the Department of Health and Human Services[9] will be used as our measure of socioeconomic status. The child's movement behaviors are designed to align with the forthcoming WHO Guidelines. The questionnaire should take 15-20 minutes for the parent to complete.

> COVID-19 Survey. Parents will be asked to complete a version of the Parent Survey related to the stay at home order that families were under due to the COVID-19 pandemic. The survey will be administered by phone when possible, and will be sent out via email using REDCap as an alternative.

Anthropometric measurements. Height and weight of each child will be measured in a private setting with children dressed in light clothing. Height will be measured to the nearest 0.1 cm using a SECA portable stadiometer. The measure will be repeated and if the two measures differ by more than 0.5 cm a third measurement will be recorded. Weight will be measured to the nearest 0.1 kg using a SECA electronic scale. The measurement will be repeated and if the two measures differ by more than 0.25 kg a third measurement will be recorded. Body mass index (BMI) z-score will be calculated based on the child's age, sex, height, and weight, then compared to the 2000 Centers for Disease Control and Prevention (CDC) Growth Charts.[10]

Physical activity. Physical activity and time spent in moderate to vigorous physical activity will be measured by a triaxial accelerometer (Actigraph GT3X+, Actigraph of Ft. Walton Beach, FL). Children will be measured by the Actigraph for 24 hours per day for 7 days. Measurements with the Actigraph will

occur for one week at baseline (before stenciling) and follow-up (6-8 weeks after stenciling). The child will be outfitted with the accelerometer on an elasticized belt, on the right mid-axillary line, and parents will be provided a handout with instructions on when and how to place the device on their child. The Actigraph is one of the most common accelerometers used for scientific purposes, and the GT3X+ version provides extensive data on steps/day and time spent in various activity intensities. During wear weeks, study staff will check accelerometry wear during school hours to assess for compliance. The minimal amount of accelerometer data that will be considered acceptable is 4 days. Following the final day of data collection, the research team will verify the data for completeness using the most recent version of the ActiLife software (version 5.6 or higher; ActiGraph, Pensacola, FL) available at the time. Established cut-points will be used to classify sedentary behavior and physical activity such as the criteria of Pate et al.[11] sedentary 0-799 counts per minute (CPM), light 800-1679 CPM, moderate 168-3367 CPM, and vigorous ≥ 3368 CPM. Other cutpoints may also be used for analyses.

The activPAL is a small device worn on the thigh by a small piece of tape. The monitors capture physical activity, sedentary time (including posture) and sleep. Children will be encouraged to wear the activPAL continuously for at least 72 hours, up to 96 hours (i.e., not take it off for any reason, including water activities [bathing, swimming] and sleeping). The monitor will be placed on the child on the first day they attend follow up assessments at the center and removed 4 days later at the center. Measurements with the activPAL will occur for 72-96 hours at follow-up only, and parents will be provided with instructions on use as well as additional tape for applying the device. ActivPALs will be distributed only to enrolled 4 year olds.

Fundamental Motor Skill Assessments. The Test of Gross Motor Development - 3rd edition (TGMD-3) will be administered with the cooperation and support of the childcare center staff in small group settings. Groups of approximately 3-4 students will complete the assessments together. The TGMD-3 uses direct observation to evaluate performance on 13 skills including running, horizontal jumping, hopping, skipping, sliding, galloping, and balls skills (two-hand striking, one-hand striking, catching, kicking, overhand throwing, underhand throwing and dribbling). The TGMD-3 involves a trained administrator demonstrating the proper execution of the skill, and the participant is allowed one practice trial, then two formal trials that will be evaluated. These assessments will be video recorded. The TGMD-3 takes 20-25 minutes to complete each group.

Ages and Stages Questionnaire (ASQ-3). Staff will complete the 'Gross Motor Skills' and 'Fine Motor Skills' sections of the Ages and Stages Questionnaire. The ASQ-3 is a developmental screener that evaluates communication, gross motor, fine motor, problem solving, and personal-social development. The full ASQ-3 takes 10–15 minutes to complete and will be performed on 4 year olds only.

Executive Functions. Three tests of executive function will be administered to children: The Early Years Toolbox (EYT) Card Sort Task, EYT Go/No-Go Task and EYT 'Mr Ant' Task. The EEYT Card Sort Task is an iPad-based assessment of cognitive flexibility - the ability to flexibly shift attention. Children are presented with cards that vary along two dimensions (i.e., shape and color) and are asked to sort each card (i.e., red rabbits and blue boats) first by one dimension (e.g., color) and then, after a number of trials, by another dimension (e.g., shape). This game takes approximately 5 minutes to complete. EYT

Go/No-Go Task is an iPad-based assessment of 'inhibition' – the ability to control behavioral urges and impulses. Children are presented with fish and sharks and are instructed to tap the iPad screen whenever they see a Fish ('catch the fish') and refrain from responding when a Shark appears ('avoid the sharks'). This game takes around 6 minutes to complete. EYT 'Mr Ant' Task is an iPad-based assessment of 'visual-spatial working memory'– the amount of visual information that concurrently can be coordinated in the mind. Children are presented with an image of a cartoon character – Mr. Ant – who has a number of colored dots placed in different spatial locations on his body. After a predetermined amount of time, these dots disappear and the child is then asked to recall the locations of the dots by tapping the corresponding locations. EYT will only be performed on enrolled 4 year olds.

Primary Endpoints and Data Analysis Plan

The primary endpoints include change in MVPA and sedentary time during recess measured by accelerometry. The secondary outcome includes change in fundamental motor skills.

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 (e.g. racial distribution of participants) will be tested using t-tests and chi-square tests. A repeated measures ANCOVA model will be used to test for effects of playground stenciling on each dependent continuous variable (minutes/recess MVPA, minutes/day MVPA in childcare center, minutes/recess Sedentary behavior, minutes/day Sedentary behavior in childcare center, minutes/day MVPA total, minutes/day screen-time total). T-tests and chi-square tests will be used to determine whether changes in outcome variables were different between the intervention and control childcare centers. Covariates will include age, sex, BMI z-score, and sociodemographic characteristics.

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 a 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. Survey items do not contain sensitive items to ensure childcare directors are comfortable responding. Anthropometric measurements and fundamental motor skill and executive functioning assessments are non-invasive and will be administered as part of the children's normal school day to eliminate burden. There are no known risks or discomforts to the child during the height and weight measurements, fundamental motor skill assessment, or executive functioning assessment. Accelerometers will be administered and worn for one week during the time the child is at the childcare center but do not pose any safety threats to subjects. At most the child may feel the monitor is uncomfortable to wear; however the device is small, lightweight, and the belt can be adjusted to make it as comfortable and easy to wear as possible. 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 or discomforts with the anthropometric measurements. We have found there is no more risk to the fundamental motor skill assessments than during typical playtime. There is no more risk to the executive functioning assessments than during typical school-based academic activities. In the unlikely event that a child experiences an injury, the assessments will be discontinued. Participants may find the accelerometers uncomfortable or bothersome to wear; however, both the Actigraph and activPAL are small, lightweight and can be adjusted to make the devices as comfortable and unobtrusive as possible. The activPAL is attached to the skin with medical grade tape that is gentle to the skin and will be administered using best practices to decrease skin irritation. If a parent responds that their child is allergic to adhesives and/or has eczema, the activPAL will not be distributed to that child. We cannot promise any direct benefits to the participant, although the stencils may provide additional opportunities for physical activity and fundamental motor skill development. Benefits of participating in this study should outweigh the risks for all participants in the study.

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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