Protocol Title: Physical Activity and Screen-Time Regulations in Childcare Centers: Influence on Young Children's Health Behaviors (Pause & Play) – Aim 2

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Objectives

A. Specific Aims

Reducing childhood obesity is identified as a top priority of the Mayor's Health City Initiative (MHCI) of Baton Rouge, Louisiana, which is a non-profit organization that brings together key community stakeholders to promote healthy living and active lifestyles. Louisiana's prevalence of obesity in preschoolers is 60% higher than the national average: 13.8% of preschoolers in the state are obese[1] compared to 8.4% nationally.[2] Obesity prevalence is particularly high among non-Hispanic black children.[2] Childhood obesity contributes to a higher risk of adult obesity, premature mortality, and comorbidities including diabetes, hypertension, ischemic heart disease, stroke, asthma, and polycystic ovary syndrome.[3] Physical activity is a protective factor against childhood obesity,[4] whereas sedentary behavior has emerged as a risk factor for obesity.[5] Yet the majority of preschoolers do not meet nationally recommended guidelines for physical activity or sedentary behavior. Less than 10% of preschoolers obtain the recommended 1 hour/day of moderate-to-vigorous physical activity.[6,7] Despite recommendations of no more than 2 hours/day of screen-time,[8] which is the most common sedentary activity among preschoolers,[9] children view on average 4.1 hours of screen-time each day.[10]

Childcare centers represent an opportunity to increase physical activity and reduce sedentary behavior in preschool-aged children, since over 80% of children spend some time in childcare settings by the age of 3 years.[10] Indeed, almost 50% of the variation in preschool children's physical activity occurs in childcare centers.[11] Yet the majority of childcare centers are conducive to low levels of physical activity and high levels of screen-time: many centers schedule little time and do not create designated space for physical activity,[12] and children spend on average 1.3 hours/day watching a screen in these centers.[9] Non-Hispanic black children and children with obesity are most likely to have both low levels of physical activity and high levels of screen time,[13] indicating that this population is particularly important to target to improve health behaviors.

Most states do not have strong regulations for physical activity or screen-time in childcare settings.[14] Louisiana's Department of Education (DOE) is implementing new regulations for children in childcare settings in 2015 to comply with national recommendations: 1) physical activity of at least 1 hour/day and 2) screen-time limited to 2 hours/day. The DOE is also providing extensive training and programmatic support to the centers. For the proposed project, the MHCI joins academic researchers at Pennington Biomedical to evaluate the implementation of these regulations and to

examine effects on children's health behaviors. During this project, we will answer three major questions: 1) are the regulations being implemented as intended; 2) do the policies benefit the intended audience; and 3) what do stakeholders identify as the most important strategies to improve children's health behaviors. The demographics of Baton Rouge provide an opportunity to examine these questions in a high risk population: 46% of city residents are non-Hispanic black and 28% of children under the age of 5 years live in households below the federal poverty level.[15]

The aims of the project are:

> **Specific Aim 2:** To examine the physical activity and screen-time behaviors of children enrolled in licensed childcare centers before and after the enactment of new state regulations.

Through this academic-community partnership, we are taking advantage of a natural policy experiment to examine the childcare environment and children's behaviors before and after implementation of a policy change. We will also facilitate conversations among stakeholders to create additional strategies to increase young children's physical activity and decrease screen-time both in childcare centers and in other settings. The overall goal is to increase physical activity and reduce screen-time among preschoolers enrolled in childcare centers. If successful, we will disseminate findings throughout the Gulf States region as a model of how changing policies in childcare settings can improve children's health behaviors and reduce childhood obesity.

Background

The Problem to Address: Obesity and Physical Inactivity in Preschool Children

The Gulf States of Louisiana, Mississippi, and Alabama each rank in the top ten for highest prevalence of childhood obesity, adult obesity, physical inactivity, type 2 diabetes, and hypertension.[16] In Louisiana, obesity affects 13.8% of children aged 3 to 5 years[1] and 29% of all children aged 2 to 17 years,[17] which is substantially higher than the national prevalence.[2] Obesity during childhood contributes to several serious comorbidities including diabetes, hypertension, ischemic heart disease, stroke, asthma, and polycystic ovary syndrome.[3] Moreover, children with obesity are at higher risk for premature mortality.[3]

Increased physical activity and decreased sedentary behavior are key recommendations to reduce the risk for obesity and related comorbidities.[18] Low levels of physical activity and high levels of sedentary activity contribute to a variety of mental and physical health consequences during the preschool and early childhood years, including obesity, high blood pressure, behavioral problems, academic problems, irregular sleep, and feelings of sadness and boredom.[9] Indeed, physical activity and screen-time together explain 65% of the variance in children's body mass index (BMI) from age 3 to 7 years.[19] However, children are not obtaining sufficient levels of physical activity and are spending too much time in sedentary pursuits. Nearly half of preschool-aged children do not meet the recommended 1 hour of moderate-to-vigorous physical activity (MVPA) each day.[7] Screens are highly prevalent in children's lives due to increased device availability and marketing efforts,[20] and preschool children are estimated to spend between 1.5 and 7.0 hours each day in screen-time[21,22] despite recommendations for 2 or fewer hours of daily screen-time.

Reducing childhood obesity is identified as a top priority of the Mayor's Health City Initiative (MHCI) of Baton Rouge, which is a non-profit organization that brings together key stakeholders in the community to promote healthy living and active lifestyles. *Pennington Biomedical has joined with the MHCI to lead a number of projects to establish the prevalence of obesity and health risk factors in the community, to evaluate simulated effects of policy changes on childhood obesity prevalence, and to coordinate medical, academic, and non-profit organizations to strategize ways to promote healthy behaviors among children and families.* This proposal represents a step forward in the partnership between the MHCI and Pennington Biomedical to empirically test the effects of a health policy aimed at improving children's health behaviors in childcare settings. Given the vast majority of preschool children attend childcare centers,[10] implementing policies that promote physical activity in these centers may have direct, impactful health benefits for young children.

A Carrot and Stick Approach to Improve Community Policies

Over the past year, the Louisiana Department of Education (DOE) has been given authority of childcare center licensing in the state of Louisiana. A 2012 state legislative mandate seeks to create a unified early childhood system under the DOE. With this transition, all licensing requirements are being revised; early care and education programs are being organized under local childcare center networks; new standards are being implemented for all childcare center providers that accept public funds; and a quality rating system is being redeveloped. Specific to the proposed project, new licensing standards will affect children attending over 1,300 licensed childcare centers state-wide and include: 1) physical activity of at least 1 hour/day and 2) screen-time prohibited for children younger than 2 years and limited to 2 hours/day for children over 2 years. Childcare centers in East Baton Rouge Parish must begin implementing changes by 2016 to renew their annual license.

In addition to the mandated regulations, the DOE is also offering new training and programmatic opportunities to help childcare centers achieve the regulations. The DOE has engaged directly with childcare centers around the state by supporting the implementation of the Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) intervention, which is funded by the state's Maternal and Child Health Title V Block Grant and 1305 funding. NAP SACC is a national evidence-based intervention to prevent and reduce childhood obesity.[23] It is implemented in childcare centers and is designed to promote healthy weight development in preschool children by improving the nutritional quality of food served, amount and quality of physical activity, staff-child interactions, nutrition and physical activity policies and practices, and related environmental characteristics. Over 200 centers have participated in the program and have integrated practices that support healthy weight behaviors since NAP SACC began in Louisiana in 2010. The Louisiana DOE will train childcare center personnel in East Baton Rouge Parish on these new regulations in 2015-16, offering a natural opportunity to examine childcare centers before and after implementation of the new policy.

Preliminary Data

Baton Rouge, which is part of the Lower Mississippi Delta (LMD), represents one of the most medically underserved, at-risk populations living in the U.S. The Louisiana LMD is characterized by high levels of poverty, food insecurity, obesity, and related

diseases. Approximately 40% of the Louisiana LMD population is African American, and 28% of residents live in poverty, compared to 12% at the national level.[15] This grant proposal arose from an ongoing collaboration between MHCI Director Mr. Allen and academic researcher Dr. Staiano, based on a shared interest to improve the health behaviors of young children in the Baton Rouge area. As part of a national effort organized by the U.S. Conference of Mayors, the MHCI was launched in Baton Rouge in response to the growing obesity epidemic and its relationship to chronic diseases which may be prevented or lessened through regular exercise and healthy eating. Community PI Mr. Allen directs the efforts of MHCI, which is a 501(c)(3) non-profit organization and includes three Advisory Boards that bring together community stakeholders on a monthly basis. As an Assistant Professor at Pennington Biomedical, a world-renowned nutrition and obesity academic research center, Dr. Staiano serves on the academic advisory board of the MHCI. Additionally, a medical advisory board and a community advisory board bring together stakeholders from area hospitals, non-profit organizations, and government agencies.

This partnership arose from several years of collaboration between Pennington Biomedical and local health organizations. From 2008-2012, Louisiana researchers and child health advocates, through the leadership of Pennington Biomedical, released an annual report card (Louisiana's Report Card on Physical Activity & Health for Children and Youth[25]) that provided grades on indicators related to children's physical activity and health. The Report Card is an advocacy tool targeting adult decision makers and is intended to increase awareness of the health concerns associated with physical inactivity, to highlight the growing problem of physical inactivity and obesity among children and youth in Louisiana, and to generate political will for policy and environmental reform. In the 2011 Report Card,[26] rather than assign grades, the Report Card research advisory committee followed the model set by the Healthy People initiative[27] and established specific targets to reach by the year 2020 for each of the report's indicators. These targets were also released for public comment. The target set for childhood obesity was a 20% reduction from baseline levels to year 2020. In 2012, a committee composed of Pennington Biomedical researchers including Dr. Staiano, as well as the lead policy analyst for chronic disease outcomes within the Louisiana Department of Health and Hospitals, and the Louisiana Director for Advocacy and Government Relations for the American Heart Association, convened to determine whether the 2020 childhood obesity target was achievable and to make evidence-based recommendations about policy approaches that would make the biggest improvements for this indicator. Our team used the Prevention Impact Simulation Model (PRISM), a systems model capable of projecting changes in obesity prevalence overall and among children.[28,29] Eight of the policy and environmental interventions considered within PRISM are interventions advocated for childhood obesity, and one of these eight focuses on physical activity in childcare centers. The PRISM model estimated that a childcare center policy to increase children's physical activity and reduce screen-time to meet recommendations would reduce overall childhood obesity prevalence by 2% by the year 2020. Given the new 2015 DOE state regulations to require physical activity and reduce screen-time in childcare centers, the MHCI's prioritization of childhood obesity prevention, and the prior work by Pennington Biomedical and the MHCI, this academic-community partnership is primed to evaluate progress towards creating healthier childcare centers in the city of Baton Rouge. The proposed project allocates resources to both the MHCI and Pennington Biomedical, using a community-based

participatory research approach to ensure findings will directly impact the local community.

Significance

We created a unique partnership between a community-based non-profit organization (the MHCI) and a world-renowned academic research institute (Pennington Biomedical) to examine the effects of a health policy change in childcare centers on children's health behaviors. The **timing is ideal** to establish baseline values of the physical activity environment and behaviors of children, then to evaluate these environments and behaviors one year after the childcare centers receive training, programmatic support, and mandated regulations to achieve the new physical activity and screen-time regulations. Community stakeholders in the MHCI have identified childhood obesity prevention as a top priority, but the majority of parents fail to recognize obesity in preschool children,[24] and many mistakenly think that obesity is not a health problem at this age. We seek a shift in the climate of the community to recognize that preschool is a critical opportunity to improve health behaviors in order to put children on a trajectory towards life-long healthy living.

Inclusion and Exclusion Criteria

From the 10 selected childcare centers, 266 children and their parent(s) will be recruited to complete additional measures of physical activity and screen-time behaviors.

Inclusion Criteria:

- A child who is 3 or 4 years old
- Child spends at least 6 hours per day, 5 days per week at a participating childcare center
- Child will continue to attend the same childcare center for the next year

Exclusion Criteria:

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

Number of Subjects and Subject Timeline

We plan to enroll 266 children. Each child will participate in the study for approximately 1 year. Surveys, anthropometric measures, fundamental motor skill assessments, and screen-time observations will take approximately 2 days to complete, and the child will be given an accelerometer to wear at home for 7 days at both baseline and 1 year follow-up. Staff members will spend approximately 2 weeks at each childcare center at baseline and 1 year follow-up to complete study procedures with each child.

Study Timeline

This study will last from March 2016 until June 2018. A proposed timeline of all study procedures is listed below:

	March to April 2016	May 2016 to April 2017	May 2017 to April 2018	May to June 2018
MOP development and IRB submission	X			
Recruitment of children		X		
Baseline data collection		X		
1 year follow-up data collection			X	
Data management and analysis		X	X	
Manuscript preparation				X

Recruitment Methods

All parents of children between the ages of 3-4 years at selected childcare centers will receive an informational handout/flyer and consent form to participate in **Aim 2** study procedures. Informational materials about the study may also be distributed to parents via email, mail, fax, phone, in-person, or through the school. Children for whom a completed consent form is returned by their parent or legal guardian will be eligible to complete additional measures of physical activity and screen-time behaviors. Out of the pool of 192 DOE licensed childcare centers, totaling a capacity for approximately 16,500 students, in EBR Parish, we do not envision difficulties enrolling 266 children for study participation. We aim to recruit all 266 children between May 2016 and April 2017.

Train Schedule

Below are the procedures that will be completed during study participation.

	Baseline 1	**Baseline 2**	**Follow-up 1**	**Follow-up 2**
Consent	X			
Parent Survey	X		X	
Height	X		X	
Weight	X		X	
BMIz score	X		X	
TGMD-3		X		X
MABC-2		X		X
Accelerometry Application	X		X	
Accelerometry Return		X		X

Procedures

Consent Process. Informed consent for the child will be obtained from one of the participant's parents/legally authorized representatives prior to conducting any study procedures. The parent/legally authorized representative will be given an informed consent form to read and sign indicating their permission to allow their child to participate in the study. Parents will return this consent form to the study staff before the

child's first visit. Because there is not a greater than minimal risk, informed consent will be obtained from one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Children will not be asked to provide documented assent due to their young age, but all procedures will be explained in child-friendly terms and a child's refusal to participate will be respected by study staff. However, if a childcare site has specific assent requirements, we will comply by creating a site-specific parental consent that includes the necessary language.

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, and employment status. The poverty guidelines developed by the Department of Health and Human Services[31] will be used as our measure of socioeconomic status.

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 1.0 cm using a portable stadiometer. Weight will be measured to the nearest 0.1 kg using high-precision electronic scale. 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.[32]

Fundamental Motor Skill Assessments. The Test of Gross Motor Development - 3rd edition (TGMD-3) and the Movement Assessment Battery for Children -2nd edition (MABC-2) 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-2 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-2 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. The MABC-2 examines eight tasks that are categorized as manual dexterity, balance, aiming and catching. This is a field-based assessment that examines correct performances on a variety of skills that are not evaluated by the TGMD-3 and will provide a holistic picture of children's motor abilities. These assessments will be audio and video recorded.

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 on 7 full days during the baseline and follow-up periods. The child will be outfitted with the accelerometer on an elasticized belt, on the right mid-axillary line. 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. Parents will be encouraged to have their child wear the accelerometer 24 hours per day for at least 7 days (plus an initial familiarization day and the morning of the final day), including 2 weekend days. During wear weeks, study staff will check accelerometry wear during school hours to assess for compliance. Accelerometer use will be documented and parents of children who do not have accelerometers on wear check days will be contacted via call, text, flyer, email, etc. as a reminder. The minimal amount of accelerometer data that will be considered acceptable is 4 days with at least 10 hours of

wear time per day, including at least one weekend day. 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. The research team will ask the parents to have the children wear the accelerometer for additional days (to a maximum of 14 days) to ensure that minimal data requirements are met. Cut points will be assigned based on Van Cauwenberghe et al.,[33] with 0 to 372 counts per minute (CPM) classified as sedentary, 373 to 584 CPM as light, 585 to 880 CPM as moderate, and ≥ 881 CPM as vigorous. MVPA will be defined as total minutes ≥ 585 CPM.

Screen time. Screen time will be assessed using classroom observation at the childcare center (from the EPAO observation in Aim 1) and parent-report for screen-time outside of the childcare center. Parents will complete a survey adapted from Jago et al.[34] to provide information about the child's screen-time (separately for TV, computer, games console and smartphone) on weekdays and weekend days. For each item the parent will be asked to report the time the child spent using it for (a) a normal weekday and (b) a normal weekend day, with response options: none; 1 to 30 minutes; 31 minutes to 1 hour; 1 to 2 hours; 2 to 3 hours; 3 to 4 hours; 4 hours or more. The assessment of TV viewing using parental report has been shown to correlate moderately (r=0.60) with 10 days of TV diaries among young children.[35]

Primary Endpoints and Data Analysis Plan

Primary endpoints will include 1) changes in objective child physical activity, as measured via 7-day accelerometer at baseline and 1 year, including minutes/day MVPA in childcare center, minutes/day MVPA total; 2) classroom observation of child screen-time, as measured with EPAO observation method to quantify average minutes/day screen-time in childcare center; and 3) parent reports of child screen time to quantity minutes/day screen-time total. Age, sex, BMI z-score, and sociodemographic characteristics will be included as covariates. We will also assess the cross-sectional and longitudinal associations among sedentary behavior (by screen-time observation/self-report and by accelerometry), physical activity (by accelerometry), and fundamental motor skills.

A repeated measures ANCOVA model will be used to test for effects of policy implementation on each dependent continuous variable (minutes/day MVPA in childcare center, minutes/day screen-time in childcare center, minutes/day MVPA total, minutes/day screen-time total). Covariates will include age, sex, BMI z-score, and sociodemographic characteristics. Correlations and a repeated measures ANCOVA will be used to test for the relationships among sedentary behavior, physical activity, and change in fundamental motor skills.

Power Analysis

A minimum of 266 children will be enrolled to ensure a well-powered study with significance level of $\alpha = 0.05$ while allowing for a dropout rate of 25% between years 1 and 2. Estimation of change was based on data from Dowda et al.,[12] which observed a significant difference between MVPA in children in preschools rated low vs. high on physical activity environment.

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. Each participant will be issued a number that will be utilized throughout the study. A secure master file linking names and participant numbers will be maintained in a confidential computer file accessible only to the investigators. Access to data files can be made only with permission of the Academic Principal Investigator. 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. 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. Survey items about the child (to be completed by the parent) do not contain sensitive items to ensure individuals are comfortable responding. During individual measurements, the study staff will ensure full privacy of participants by taking measurements in a private or semi-private area (ex: the nurse's office or a separate room) with only the participant and researcher present (unless the school requires for a teacher/nurse to be present). 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.

Data will be stored in a secured area and all study staff must be HIPAA certified. Following transcription of the TGMD-3 and MABC-2, all recordings will be de-identified and original audio/video tapes that contain names and images will be destroyed, to occur no later than 3 years after the study ends. Only pertinent study staff will have access to study data.

Withdrawal of Subjects

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

- Unwillingness on behalf of the parent/child to participate in the study or cooperate with study staff

Risks to Subjects

We have found there is no more risk to the fundamental motor skill assessments than during typical play time. There are no foreseeable risks or discomforts with the anthropometric measurements. In the unlikely event that a child experiences an injury, the assessments will be discontinued. Participants may find the accelerometer uncomfortable or bothersome to wear; however; the accelerometer is small, light, and comes with an adjustable strap to make the device as comfortable and unobtrusive as possible.

Potential Benefits to Subjects

Participants may experience changes in physical activity and screen-time due to the policy changes in their childcare center. Benefits of participating in this study should outweigh the risks for all participants in this study.

Vulnerable Populations

This study will involve young children as participants (3-4 year olds). As such, the parent/legally authorized representative will provide written informed consent allowing the child to participate in individual study procedures. Due to the young age and lack of cognitive/decision-making capacities of this age group, participants will not be asked to provide documented assent; however, all procedures will be explained in child-friendly terms and a child's refusal to participate will be respected by study staff.

All participants will be explicitly told that their participation is voluntary and that they may terminate their participation at any time. If a participant indicates that they wish to stop participating, all study procedures they are undertaking at that time will be stopped to protect their rights and welfare.

Sharing of Results with Subjects

Study results will not be shared with participants unless requested. If requested, individual results may be made available.

Setting

All 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., *Academic 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 screen-time and public policy related to children's health.

Elizabeth "Kip" Webster, Ph.D., *Co-Investigator,* is an Assistant Professor in the School of Kinesiology at Louisiana State University. Dr. Webster is a pediatric motor developmentalist and physical activity specialist with expertise in measuring and assessing health behaviors in young children. She previously assisted with the revisions of the 3rd edition of the Test of Gross Motor Development (TGMD) as a Postdoctoral Research Fellow at the University of Michigan. Dr. Webster will provide training and facilitate the fundamental gross motor skills assessments (TGMD-3 and MABC-2).

Corby Martin, Ph.D., *Academic Mentor*, Associate Professor, is a licensed clinical psychologist with extensive experience conducting population-based cluster randomized trials, including an ongoing clinical trial to test a home-based obesity intervention for preschool children. As a senior faculty member, Dr. Martin will provide ongoing mentorship to Dr. Staiano.

Andrew T. Allen, B.A., *Community Consultant*, is the Director of the Mayor's Healthy City Initiative and Community Outreach Coordinator for the Office of the Mayor-President in the City of Baton Rouge.

Additional staff members, including a PBRC project coordinator, a PBRC research specialist, and policy student worker located at the Mayor-President's Office will oversee data collection and conduct the focus groups.

Both principal investigators have extensive networks to childcare centers throughout the city. Staff members will spend at least 2 weeks in each childcare center at baseline and 1 year later to establish rapport for recruitment and data collection. There are currently 192 licensed childcare centers and 13 Head Start centers located in EBR Parish. These available childcare centers in EBR Parish provide a capacity for approximately 16,500 students, so we do not envision difficulties recruiting 266 children between the ages of 3-4 years old for individual assessments out of this large possible pool of children available at DOE licensed childcare centers in EBR Parish.

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 study procedures will take place at the childcare center during normal hours or at home in conjunction with normal, everyday activities, and will not add any economic burden on the participants. Thus, no monetary compensation will be provided to participants or their parents. Participants will receive a handstamp or sticker as a reward for completing the anthropometric measures and returning their accelerometer. Handstamps and stickers are extremely rewarding items that are well-received by children of this age, whereas additional compensation could be coercive for children of such a young age.

Drugs or Devices

N/A

References

1. Polhamus B, Dalenius K, Borland E, Mackintosh H, Smith B, Grummer-Strawn L. Pediatric nutrition surveillance 2007 report. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, 2009.
2. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the united states, 2011-2012. *JAMA.* 2014;311(8):806-814.
3. Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and adolescence on morbidity and premature mortality in adulthood: systematic review. *Int J Obes.* 2011;35(7):891-898.
4. Ekelund U, Luan J, Sherar LB, Esliger DW, Griew P, Cooper A. Moderate to vigorous physical activity and sedentary time and cardiometabolic risk factors in children and adolescents. *JAMA* 2012;307(7):704-712.
5. Tremblay M, LeBlanc A, Kho M, et al. Systematic review of sedentary behaviour and health indicators in school-aged children and youth. *Intn J Beh Nutr Physical Activity.* 2011;8(1):98.
6. National Association for Sport and Physical Education. *Active Start: A Statement of Physical Activity Guidelines for children from Birth to Age 5, 2nd Edition*: Physical Education, Recreation, and Dance; 2009.
7. Beets MW, Bornstein D, Dowda M, Pate RR. Compliance With National Guidelines for Physical Activity in U.S. Preschoolers: Measurement and Interpretation. *Pediatrics.* 011;127(4):658-664.
8. The American Academy of Pediatrics Council on Communications Media. Policy Statement -- Children, Adolescents, Obesity, and the Media. *Pediatrics.* 2011;128(1):201-208.
9. Vanderloo LM. Screen-viewing among preschoolers in childcare: a systematic review. *BMC Pediatr.* 2014;14:205.
10. Tandon PS, Zhou C, Lozano P, Christakis DA. Preschoolers' total daily screen time at home and by type of child care. *J Pediatr.* 2011;158(2):297-300.
11. Pate RR, Pfeiffer KA, Trost SG, Ziegler P, Dowda M. Physical activity among children attending preschools. *Pediatrics.* 2004;114(5):1258-1263.
12. Dowda M, Pate RR, Trost SG, Almeida MJC, Sirard JR. Influences of preschool policies and practices on children's physical activity. *J Commun Health.* 2004;29(3):183-196.
13. Anderson SE, Economos CD, Must A. Active play and screen time in US children aged 4 to 11 years in relation to sociodemographic and weight status characteristics: a nationally representative crosssectional analysis. *BMC Public Health.* 2008;8(1):366.
14. Larson N, Ward DS, Neelon SB, Story M. What Role Can Child-Care Settings Play in Obesity Prevention? A Review of the Evidence and Call for Research Efforts. *J Amer Diet Assn.* 2011;111(9):1343-1362.
15. U.S. Census Bureau. American FactFinder, 2014. *Available at: http://factfinder.census.gov* 2014.
16. Trust for America's Health and Robert Wood Johnson Foundation. *The State of Obesity 2014.* Washington, D.C.2014.
17. Romero P LCoOPaM. Overweight and obesity data from the Department of Health and Hospitals Adolescent School Health Program - Louisiana School Based Health Centers. 2010.
18. U.S. Department of Agriculture. Dietary Guidelines for Americans, 2010.
19. Jago R, Baranowski T, Baranowski J, Thompson D, Greaves K. BMI from 3-6 y of age is predicted by TV viewing and physical activity, not diet. *Int J Obes Relat Metab Disord.* 2005;29(6):557-564.
20. Strasburger VC, Hogan MJ, Mulligan DA, et al. Children, adolescents, and the media. *Pediatrics.* 2013;132(5):958-961.
21. Rideout VJ, Foehr UG, Roberts DF. *Generation M2: Media in the lives of 8- to 18-year-olds.* Menlo Park, California, 2010.

22. Heelan KA, Eisenmann JC. Physical activity, media time, and body composition in young children. *J Physical Activity & Health.* 2006;3(2):200.
23. Benjamin SE, Ammerman AS, Ward DS, et al. Peer Reviewed: An Intervention to Promote Healthy Weight: Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) Theory and Design. *Prev Chronic Dis.* 2007;4(3).
24. Lundahl A, Kidwell KM, Nelson TD. Parental Underestimates of Child Weight: A Meta-analysis. *Pediatrics.* 2014;133(3):e689-e703.
25. Pennington Biomedical Research Center. Louisiana's Report Card on Physical Activity & Health for Children & Youth: Past Report Cards. http://www.pbrc.edu/report_card/past/. Accessed January 15, 2015.
26. Pennington Biomedical Research Center. Charting the Course for 2020: 2011 Louisiana's Report Card on Physical Activity & Health for Children and Youth. http://www.pbrc.edu/report_card/pdf/2011%20LA%20Report%20Card%20Long.pdf. Accessed January 15, 2015.
27. Centers for Disease Control and Prevention. Healthy People. http://www.cdc.gov/nchs/healthy_people.htm. Accessed January 15, 2015.
28. Homer J, Milstein B, Wile K, Pratibhu P, Farris R, Orenstein DR. Modeling the local dynamics of cardiovascular health: risk factors, context, and capacity. *Prev Chronic Dis.* 2008;5(2):A63.
29. Homer J, Milstein B, Wile K, et al. Simulating and evaluating local interventions to improve cardiovascular health. *Prev Chronic Dis.* 2010;7(1):A18.
30. Bower JK, Hales DP, Tate DF, Rubin DA, Benjamin SE, Ward DS. The childcare environment and children's physical activity. *Amer J Prev Med.* 2008;34(1):23-29.
31. U.S. Department of Health and Human Services. The 2008 HHS poverty guidelines. 2010; http://aspe.hhs.gov/poverty/08Poverty.shtml. Accessed February 20, 2015.
32. Centers for Disease Control and Prevention. A SAS program for the CDC growth charts. 2011; http://www.cdc.gov/nccdphp/dnpao/growthcharts/resources/sas.htm. Accessed February 20, 2015.
33. Van Cauwenberghe E, Labarque V, Trost SG, De Bourdeaudhuij I, Cardon G. Calibration and comparison of accelerometer cut points in preschool children. *Int J of Pediatr Obes.* 2011;6(2Part2):e582-e589.
34. Jago R, Thompson J, Sebire S, et al. Cross-sectional associations between the screen-time of parents and young children: differences by parent and child gender and day of the week. *Int J Behav Nutr Physical Activity.* 2014;11(1):54.
35. Anderson D, Field D, Collins P, Lorch E, Nathan J. Estimates of young children's time with television: a methodological comparison of parent reports with time-lapse video home observation. *Child Dev.* 1985;56(5):1345 - 1357.
36. McKenzie, T. L., Marshall, S. J., Sallis, J. F., & Conway, T. L. (2000a). Leisure-time physical activity in school environments: An observational study using SOPLAY. Preventive Medicine, 30, 70-77.