Protocol Title: *PLAY: An Intervention to Improve Motor Skills in Young Children*

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Preschoolers spend 4 hours/day in front of a screen,[1] while fewer than one-quarter engage in the recommended two hours of daily physical activity (PA).[2, 3] The decline in PA, increase in screen-based behaviors, and onset of obesity during preschool years have been linked to lifetime risk of obesity and related comorbidities.[4, 5] However, emerging evidence indicates that "screen time" can actually be leveraged as a tool to increase children's PA and promote healthy weight. Specifically, PA interventions delivered over digital devices can provide real-time encouragement for children to be physically active. Prior interventions delivered over mobile devices were effective in increasing PA levels, including our own P-Mobile study that provided behavioral strategies to parents of children aged 6 to 10 years.[6, 7]

When considering how to support and motivate parents whose children are preschool-aged, teaching and modeling **fundamental motor skills (FMS)** are critical to enable children's PA.[8, 9] FMS like running, jumping, or throwing a ball, are basic, goal-directed movement patterns developed in early childhood that provide a foundation for children to be physically active and competent movers.[10] These skills enable a child to function independently in their surrounding environment, engage with peers, and contribute to their ability to be physically active.[8, 10] Evidence has shown that children must establish a minimal level of FMS proficiency to continue participating in PA opportunities as they age.[8, 9, 11-13] FMS and PA behaviors have a dynamic and reciprocal relationship.[8, 9] Children with higher levels of FMS are more physically active both during childhood [14-16] and into adolescence.[17-20] Research has indicated that the preschool years are an opportune time for children to learn and reinforce these skills.[21] However, our preliminary data indicate that children in our community are in the 32nd percentile for FMS based on their age. With inadequate FMS competency, a child is less likely to engage in physical activities based on lack of prerequisite skills and abilities that are foundational to FMS,[8, 9, 11-13] whereas a child with adequate FMS competency tends to be more physically active and less likely to be overweight or obese.[22] Indeed, the PA trajectory model[8] indicates that FMS competence is a critical component to a child's risk of obesity and contributes to PA, physical fitness, and perceived movement competence.[9] Moreover, FMS promote self-regulatory abilities including managing emotions, focusing attention, and inhibiting behavior.[23] Behavioral self-regulation is important for academic readiness,[24] coping with stress, and regulating health behaviors that contribute to obesity.[25] Therefore, a PA intervention for preschoolers should focus on developing FMS competence.

The goal of "PLAY" is to adapt and test a developmentally appropriate intervention delivered on a mobile app to parents, with the goal of teaching FMS proficiency to their preschool-aged children (ages 3 to 5 y). We will randomize up to 74 child-parent dyads (children 3 to 5 y of age) to this intervention, with up to 37 parents using the FMS app and up to 37 using a version of the app that promotes unstructured PA as a comparator group. Parents in the FMS condition will access instructional lessons, peer modeling videos, and activity breaks to deliver 720 minutes of targeted, *structured FMS instruction time* to their child over a 12-week period (12 min/day, 5 days/week). Parents in the comparator arm will use a version of the app that provides instructional lessons to promote the equivalent amount (12 min/day, 5 days/week over 12-weeks) of *unstructured PA* for their child. Parents will guide the intervention, as parental support, modeling, and co-participation predict children's engagement in PA.[26-29]

The specific aims are as follows:

Specific Aim 1: To examine the feasibility and acceptability of a 12-week FMS intervention delivered through a mobile app to parents and children.

Specific Aim 2: To test the hypothesis that a 12-week FMS intervention delivered through a mobile app will improve children's FMS, compared to the unstructured PA app comparator group.

Exploratory Aims: To test the hypothesis that a 12-week FMS intervention delivered through a mobile app will improve children's PA levels, perceived movement competence, and academic readiness (i.e. self-regulation skills), compared to the unstructured PA app comparator group; to examine FMS as a mediator of changes in PA levels; and to examine sustained effects on outcomes 12-weeks following the end of the intervention.

This project provides a unique contribution by furthering our understanding of how a parent-targeted, app-based intervention that targets FMS development impacts children's FMS, PA levels, perceived movement competence, and academic readiness. Given the ubiquity of digital devices in parents' and children's daily lives, this project will provide important information on whether or not, and in what ways, apps may serve as an intervention tool to educate, prompt, and promote FMS development and PA in children while providing the informal, fluid, and social learning environment that is most comfortable to young children and their parents.

Inclusion and Exclusion Criteria

Inclusion Criteria (child):

- 3-5 years of age
- Physically capable of exercise
- Has no parent-reported mobility limitations that impairs performance of fundamental motor skills

Exclusion Criteria (child):

- Gross Motor Quotient at "gifted or very advanced" based on the Test of Gross Motor Development (TGMD-3)

Inclusion Criteria (parent):

- Has a smart phone
- Willing to download and use the app
- Has no plans to move outside the greater Baton Rouge area during the study period
- Has no self-reported mobility limitations that impairs modeling of fundamental motor skills

Number of Subjects

The participants in this study will be up to 74 dyads, each consisting of one child and one parent (up to 144 persons total). If the parent has multiple qualifying children, the parent must select one eligible child to enroll in the study. The demographics of Baton Rouge provide an opportunity to examine this intervention in a high-risk population, given 46% of city residents are non-Hispanic black and 28% of children under the age of 5 live in households below the federal poverty level.[30] We will not limit the intervention based on income level but rather recruit from the general population, with the goal to test the feasibility and effectiveness for generalizability.

Recruitment Methods

We will use multiple strategies that were effective in our prior pediatric trials, including but not limited to advertising in preschools and via community and church organizations and using email newsletters, list serves, and social media. Members of the investigative team have been directly involved in successful pediatric recruitment, collectively recruiting 4500 children into PA-related research.

Study Timelines

See **Table 1** below for the detailed study timeline. The first half of Year 1 will be used to finalize the intervention protocol and adapt the app, while the second half will be used to begin recruitment and the intervention. The anticipated duration to enroll all study participants will be 12 months. The data collection period is anticipated to last approximately 15 months. Data will be analyzed and published in the final half of Year 2.

Table 2. Study Timeline

	Year 1				Year 2			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
App Adaptation and Usability Testing								
Finalization of Protocol, Surveys, and Consents								
App Internally Tested and Ready to Launch								
IRB Approval								
Training of Study Staff								
Screening Visits								
Week 0 Baseline Assessments and Randomization								
Intervention								
50% Enrollment Complete								
100% Enrollment Complete								
Week 12 End of Intervention Assessments								
Week 24 Follow-Up Assessments								
Data Collection Complete								
Data Analysis								
Paper Submission								
R01 Submission								

Procedures Involved

Telephone Screen. Research staff will perform a phone screen with parents to determine initial eligibility.

Screening visit. Research staff will conduct screening, consenting, and assessments in YMCA branches or other community locations, strategically chosen for convenience to the majority of residents, available classroom space for assessments, and our prior history of conducting research assessments in these sites. The parent will sign the consent form. Assessments may be scheduled in the afternoon/evening hours and Saturdays as convenient for the parents. The parent/child will be formally oriented to the study during this visit and receive detailed information on the purposes, goals, procedures, and timeline. Parents will confirm that they and their child have no mobility limitations, and children will complete the TGMD-3 to confirm eligibility. The parent will receive an accelerometer for the child to wear for 7-days.

Baseline visit (week 0). Within 2-3 weeks of the screening visit, children will return to the YMCA or community location for anthropometric assessments and the perceived movement skill competence survey, and parents will return the accelerometer and complete surveys. In advance of randomization, Co-I and statistician Dr. Beyl will generate a sex-stratified adaptive randomization taking into account baseline FMS. The study staff will help to download the app onto the parent's smartphone/tablet and select the FMS version or unstructured PA version based on randomization. If participant cannot attend the Baseline visit within 3 weeks of the Screening visit, screening measures must be repeated.

End of treatment visit (week 12) and follow-up (week 24). The child/parent will return to the YMCA or community location to complete assessments at end of intervention (+/- 1 week) and again 12-weeks later (+/- 2 weeks). Assessments include the TGMD-3, anthropometry, and the perceived movement skill competence. The parent will complete surveys and return the accelerometer (which will be mailed to the parent 2 weeks prior to the visit for the child to wear for 7-days). At the week 12 and week 24 visits, the accelerometer will be downloaded to ensure wear compliance was met. If the child did not meet wear time compliance, they will counselled on compliance and will be issued another accelerometer to wear for 7 days along with a pre-stamped envelope to mail it back to Pennington.

PLAY App

The PLAY app (which contains a FMS section and unstructured PA section) is developed by an app development company which will create the app using the content and videos developed by the investigators during the first 6 months.

Usability testing will include up to 8 parents not enrolled in the study who will beta test the app. Of those, up to 4 will be randomly assigned to the Unstructured Play Condition and up to 4 will be randomly assigned to the Fundamental Motor Skill Condition. Usability testing will be conducted with parents from the Baton Rouge area who have children that are 3-6 years of age. Parents will be asked to come to a 1 hour visit where study staff will download the fully programmed app to their smartphones. Parents will be asked to use the app for up to four weeks. After completing the usability testing, parents will be asked to complete an exit interview over the phone or in person where study staff will collect information on the acceptability and feasibility of the app.

They will also be asked to rate their satisfaction of the app with regards to design, appeal, and functionality by completing a survey. The phone interview will also collect feedback regarding suggestions for app improvement and users' impressions of the app notifications. App usage data will be collected by the software company and provided to PBRC. Parents who complete usability testing will be compensated a total of $50.00. After field usability has concluded, the software company will incorporate the improvements to the app and resolve any remaining issues. Parents who complete usability testing will be consented separately and will not be eligible to complete the main study.

Parents in both conditions will download and use the PLAY app during the main study. To standardize the appearance and usability of the app across the two conditions, the two versions of the app will mimic each other in terms of design and layout. Parents in the FMS condition will have access to the FMS instructional lessons, peer modeling videos, and activity breaks to deliver 720 minutes of targeted, structured FMS instruction time to their child over a 12-week period (12 min/day, 5 days/week). Parents in the Unstructured PA (defined as free play that is encouraged by not dictated/guided by parents) condition will have access to the unstructured PA lessons and videos to promote the equivalent amount (12 min/day, 5 days/week over 12-weeks) of unstructured PA for their child.

All communication with parents (outside of assessment visits) will occur via mobile device (smartphone or tablet/iPad). However, if usage data indicate that the parent is not regularly using the app, a research staff member may call the parent to ensure there are no technical difficulties. Push notifications will be sent via the app to prompt the parent to read each week's lesson (1x/week) and to prompt the parent and child to engage in the activity break (4x/week). The principles of shaping[33] will be used to employ a reinforcement schedule to promote continued motivation for the child during the 12-week intervention. At the baseline visit following randomization, the parent will be instructed by the research staff on how to provide reinforcement to their child in the form of a reinforcement schedule. The reinforcement schedule is based on a reward system in which the child earns stars for each day they complete a 12-minute break. Parents will have the option to provide non-food rewards to their children as they complete 5 stars each week. See similarities and differences of each condition in **Table 2**.

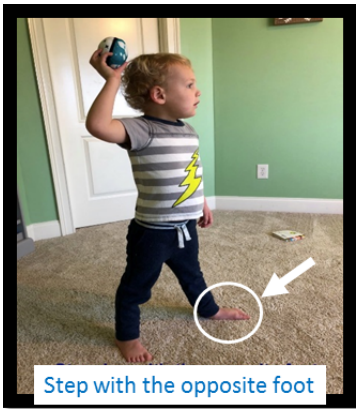
Table 2. PLAY App: Features of each condition.

	Fundamental Motor Skills	**Unstructured Physical Activity**
Child Physical Activity	720 min of directed instruction on motor skills over 12 wks (12-min/d, 5 d/wk)	720 min of unstructured PA over 12 wks (12-min/d, 5 d/wk)
Parent Lesson	Parent reads lesson 1x/week on each targeted FMS (e.g. description of a proficient "hop")	Parent reads lesson and watches voice-over powerpoint slide with lesson 1x/week on PA support (e.g. how to make time for PA)
Peer Modeling Videos	Parent and child watch video of peers modeling each targeted FMS (e.g. performing a "hop")	None
Activity Break	Practice, modeling, and reinforcement of each targeted FMS (e.g. hopping game)	Free play examples of unstructured PA (e.g. take child to the park, play songs for a dance party)
Push Notifications	5x/wk to prompt each new lesson and 12-min activity break	
Rewards and Reinforcement	Point system reinforcement schedule	

Fundamental motor skill condition. Parents in the FMS condition will be provided access to the FMS features on the app, following a 12-week curriculum focused on six key FMS (3 locomotor, 3 object control) that we selected to be challenging but developmentally appropriate (i.e. hop, throw, slide, kick, vertical jump, catch; each taught over one week during weeks 1-6 and then repeated during weeks 7-12). Parents will assist the child in the engagement of at least 12 min of structured FMS practice daily, 5 days/week, including viewing videos and practicing the skills through the activities described on the app. For example, on Week 1 Day 1, the parent will receive a push notification to open the app and access the first themed lesson, "Hop." The parent will read a brief instructional lesson about the targeted FMS, including a description of a proficient "hop." The parent and child will then view a brief video of the demonstrated FMS, and then engage in a 12-min activity break designed to help the parent model the skill and provide the child with practice. Total exposure will accumulate to 720 min of directed instruction over 12 weeks, a dosage that aligns with prior interventions that effectively improved children's FMS.[34, 35]

Theoretical basis. Behavioral scaffolding[81] and social cognitive theory[36, 37] informs the FMS approach. The child and parent learn by viewing a series of video segments of children performing motor skills that increase in complexity. Behavioral scaffolding is a cognitive learning approach to problem solving that allow children to master skills beyond his or her current ability[38, 39] and is effective in helping parents assist children in attaining behavior goals.[40] According to social cognitive theory, for modeling to effectively elicit behavior change, the child must undergo a process involving attention, retention, reproduction, and motivation.[36, 37] Attention is garnered through the app via videos of peers with auditory and visual stimuli to enhance arousal/engagement. Retention is reinforced through multiple exposures to the video segments along with push notifications to parents (SMS text message) to reinforce behavioral change strategies including FMS practice. Reproduction is elicited through the child producing the modeled activities. Motivation is encouraged intrinsically through perceived competence and extrinsically via encouragement in the form of video and text files.

Peer modeling videos and behavioral scaffolding. Brief videos viewed by the parent and child will be used as a model to provide scaffolding for the child to improve FMS competency. Our team has begun recording brief videos of preschool-aged children (diverse in age, sex, and race/ethnicity) modeling 6 FMS, with each video demonstrating 5 progressively more difficult process-oriented components of the skill (30 videos in total). Additional brief videos provide examples of the games and activity breaks. Scaffolding personalizes the experience such that the child is rewarded for mastering the demonstrated skill, allowing the parent to move on to the next video in the app. For example, for overhand throw children will begin with a contralateral step, then wind-up, followed by trunk rotation/follow through. Prompts appear on each video to provide clear, concrete criterion to trigger the parent to advance to the next video (e.g. "Once your child is stepping with the opposite foot (see video) you can move to the next stage"). Once the child masters one performance component, which will be highlighted by graphics on the video (e.g. an arrow pointing to



the opposite foot), parents advance to the next level and the child receives reinforcement through visual cues. If the child has trouble mastering a skill, modifications are available to minimize frustration (e.g., jump on both legs if the child cannot hop on one leg). If the child reaches mastery, the final video for each skill encourages improved motor performance (e.g. a higher hop or longer throw) to avoid boredom or ceiling effect.

Activity breaks. The final component of each lesson is that the parent will guide the child through a 12-min activity to practice, model, and reinforce the targeted FMS with games/activities (see **Table 3**). mPI Webster developed and tested these lessons, demonstrating effectiveness to improve children's motor skill competence with good adherence.[41, 42] A list of activities will be provided that allow the parent and child to practice the demonstrated skill together with minimal equipment (e.g. "Red Light, Green Light").

Table 3. Activity break for "Hop"

- Warm-up: Flamingo stand (30 sec for each foot)
- A. Scissor jumps (30 sec)
- B. Hop scotch hopping (30 sec)
- C. Squats (30 sec)
- D. Lava jump! (30 sec)
- Repeat A-D 5 times
- Cool-down: Balancing act (1 min)

Unstructured PA condition. Parents in the comparator group will access content on the app that provides 12-weeks of lessons with ideas for free play to promote their child's unstructured PA. These lessons are adapted to be developmentally appropriate for preschoolers using the curriculum we previously developed and tested based on social cognitive theory.[6] We selected this comparator arm as it has shown to increase children's PA levels[6] but does not explicitly target FMS or provide structured lessons to parents on how to model these skills. The following six topics will be covered: stimulus control, making time for child's free PA, being active in- and outdoors, reinforcing PA, reducing sedentary behaviors, and parental co-participation. The free play breaks will provide specific strategies to encourage the child's unstructured PA (e.g. take your child to the park or outside, use your phone alarm to remind your child to be physically active).

Table 4. Study Procedure Schedule

	Screening Visit	**Baseline (Week 0)**	**Intervention**	**End of Treatment (Week 12)**	**Follow Up (Week 24)**
Consent	**X**				
Anthropometric Measures		**X**		**X**	**X**
Parent Surveys	**X**	**X**		**X**	**X**
Child Survey		**X**		**X**	**X**
TGMD-3	**X**			**X**	**X**
Accelerometer (distribute)	**X**				
Accelerometer (return)		**X**		***X**	***X**
Randomization		**X**			
PLAY App download		**X**			
PLAY App use (12 weeks)			**X**		

*Accelerometer will be mailed to parents approximately 2 weeks prior to Wk 12 and Wk 24 visits

for the child to wear for 7 days

Study Endpoints

Primary Outcomes. *Feasibility* will be measured as adherence to the app intervention, including number of lessons/videos and activity breaks/videos accessed and frequency of interaction with the app. During each week of the intervention, parents will complete an *acceptability* survey over the app to assess satisfaction and usability. At the end of the intervention, parents will complete an acceptability survey to assess overall satisfaction and usability.

FMS will be assessed using the Test of Gross Motor Development (TGMD-3), a direct observation assessment used with children ages 3–10 y. The TGMD-3 is a process- and product-oriented assessment to evaluate FMS performance in two subscales: locomotor (run, gallop, one-legged hop, skip, jump, and slide) and ball skills (two-hand strike, one-hand strike, catch, kick, dribble, overhand throw, and underhand throw). By design, these include skills targeted in the intervention. mPI Webster demonstrated that the TGMD-3 is a valid and reliable assessment tool.[43, 44] Assessments will be filmed and coded by trained research assistants blind to the purpose of this project who have reached 98% reliability coding sample administrations prior to testing. At the Week 24 visit, participants may be asked to perform three additional motor skill tasks: Supine-Timed Up and Go (S-TUG), One-leg Standing Balance Test, and the Standing Long jump.

Exploratory Outcomes. *Physical activity levels.* The child will wear an Actigraph GT3X+BT accelerometer for 7-days on the right hip, which has been validated in preschoolers.[45] Minimal wear time is 4 days with ≥10 hours/day (≥1 weekend day) and 15-sec epoch length.[46] We will use the cutpoints by Pate et al.[45] to classify moderate and vigorous PA, which were validated in preschoolers against indirect calorimetry,[45] and the sedentary cutpoint by Evenson et al.,[47] which was validated in preschoolers against direct calorimetry.[48]

Perceived movement competence. The Pictorial Scale of Perceived Movement Skill Competence[49, 50] will examine a child's perceived movement competence on the 13 skills assessed with the TGMD-3[49] and takes approximately 10 min for the child to complete. mPI Webster has established reliability with this scale.[49]

Self-regulation skills/academic readiness. Self-regulation skills will be measured by the parent using the Devereux Early Childhood Assessment (DECA), 2nd Edition, which is a 38-item proxy report with good validity and reliability to measure self-regulation and behavioral concerns in children 3 to 5 y.[51]

Anthropometry. Height and weight will be measured using a stadiometer and portable scale, without shoes, and recorded to the nearest 1.0 cm and 0.1 kg. BMI z-score will be calculated.[52]

Sociodemographic information and health behaviors. Parents will provide information on child's and parent's age, sex, race/ethnicity, parental education, food security, time spent in away-from-home care, family structure, home environment, and household income, as well as health behaviors including media use, prior experience with apps, family participation in physical activity, and eating habits.

Household Chaos Questionnaire. Parents will complete the Confusion, Hubbub, and Order scale (CHAOS). This 15-item questionnaire will assess household organization, noise level, and crowding. [53]

Power analysis.

The estimated effect size is based on a meta-analysis of FMS interventions (overall effect size *d*=0.39).[34, 54] A group size of 28 dyads/group will provide 80% power to detect an effect size of 0.33 for change in FMS score at week 12 (α=0.05). We will randomize up to 37 dyads/group (total of up to 74 dyads) and assume 20% of dyads will drop out by week 12 so that there will be up to 30 dyads/group at end of intervention.

Data Analysis

We use intent-to-treat mixed effect linear models. Aims 1 and 2 will be assessed using the least square means for the treatment effect from the model. We will include covariates to test if biological variables, such as sex, are associated with outcomes. We will use mediational analyses to further isolate the effects of FMS changes on exploratory outcomes and mixed effect linear models to examine sustained changes at week 24. Children will be included regardless of developmental delay, as both typically and atypically developing children benefit similarly from FMS interventions.[34]

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. Dr. Webster's lab will also be responsible for data analysis of the TGMD data. 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 Principal Investigator. All electronic data will be stored in the secure Pennington database and with Dr. Webster's lab, 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

A. Data Quality and Management
   1) Description of Plan for Data Quality and Management – The PIs and Project Manager will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. A statement reflecting the results of the review will be sent to the NIH in the annual report (non-competing continuation). Any protocol deviations will be reported to the PBRC IRB. Although there are additional reports to be produced by the study coordinator as a result of this DSMP, there are no substantive changes to the study protocol that might require review by the NIH.
   2) Frequency of Review – The types of data reviewed and frequency of review are detailed in the table below.

Data type	Frequency of review	Reviewer
Subject accrual and protocol adherence	Quarterly	Principal Investigators, Independent Monitor
Adverse event rates	Semi-annually	Principal Investigators, Independent Monitor, DSMB
Rates of study completion	Quarterly	Principal Investigators, Independent Monitor
Stopping rules report regarding statistical power implications of drop outs and missing data	Yearly	Principal Investigators, Independent Monitor, Biostatistician, DSMB

B. Subject Accrual and Compliance
   1) Measurement and reporting of subject accrual, adherence to inclusion/exclusion criteria, protocol adherence, and rates of study completion – Review of subject accrual, adherence to inclusion/exclusion criteria and study procedures as listed in the protocol, and rates of study completion will occur quarterly. These data will be reviewed by the study PIs and Independent Monitor.
   2) Stopping Rules – Data on subject accrual and completion rates will be synthesized and evaluated yearly to determine if the study should be terminated. One of the most likely reasons for early termination is the failure to recruit or retain participants; therefore, these data will be evaluated yearly to determine if failure to recruit or attrition is jeopardizing the ability to empirically test the study aims. These data will be reviewed by the study PIs and Independent Monitor, with consultation from the statistician, and by the DSMB.
   3) AE rates and out of range data – AE rates will be evaluated quarterly and out of range data will be evaluated yearly by the study PIs, Independent Monitor, DSMB, and the institution's pediatric medical investigator, Dr. Hsia, to ensure proper AE reporting and to regulate procedures to protect participant safety.

C. Stopping Rules – This study may be stopped prior to its completion if: (1) adverse events that significantly impact the risk-benefit ratio have been observed; (2) study recruitment or retention becomes futile; (3) any new information becomes available during the trial that necessitates stopping the trial; and (4) other situations occur that might warrant stopping the trial. The PIs will include assessments of AEs and recruitment futility in the annual progress report to NIH to monitor these variables. The PIs will consult with the statistician if necessary to assess the impact of significant data loss due to problems in recruitment, retention, or data collection.

D. Designation of an Independent Monitor – Mandy Shipp, Director of Clinical Regulatory Affairs at Pennington Biomedical, has been designated as the independent monitor for this study. Ms. Shipp has worked at Pennington Biomedical for over 14 years. She has served on numerous Data and Safety Monitoring Boards

and has served as the Safety Officer. She is not in either PI's chain of command and is not involved with the study.

E. Safety Review Plan – Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports, including patient recruitment, retention/attrition, and AEs will be provided to the Independent Monitor and reviewed quarterly, as outlined above. An annual report will be compiled and will include a list and summarization of adverse events. In addition, the annual report will address (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The annual report will be signed by the study PIs and Independent Monitor and will be forwarded to the DSMB, PBRC IRB, and NIH to review the progress of this study on an annual basis.

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: a separate room) with only the participant and researcher present. The parent 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, all recordings will be de-identified and original audio/video tapes that contain names and images will be destroyed, to occur no later than 5 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 levels while using the PLAY app. 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 (3-5 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 at local YMCAs or other community venues. Parents will utilize the PLAY app on their smartphone or tablet in their homes or other settings during free-living conditions.

Resources Available

The project team for this single-site study is fully equipped to execute the proposed project with expertise in exercise, psychology/behavior change, pediatrics, and biostatistics. The team has extensive experience conducting pediatric and family-based physical activity promotion research.

Amanda Staiano, Ph.D. (mPI) is Assistant Professor and Director of the Pediatric Obesity and Health Behavior Laboratory. She is a developmental psychologist who contributes experience in designing and implementing family-based weight management interventions, including RCTs and prospective cohort studies of over 1500 children and adolescents (e.g. NIH U54 MD 008602-P02UAB, USDA 3092-51000-056-04A, AHA 15GRNT24480070). As mPI, Dr. Staiano will be fully responsible for the day-to-day management of the project, she will manage enrollment, retention, and fidelity to the intervention protocol, and she will supervise progress towards meeting the project's timeline.

E. Kipling Webster, Ph. D. (mPI) is an Assistant Professor at Louisiana State University within the School of Kinesiology. Dr. Webster will manage the fundamental motor assessments, she will create the instructional content and fundamental motor skill videos for the app-based intervention, and she will supervise progress towards meeting the project's timeline.

Robert Newton, Ph.D. (Co-I) is Associate Professor and Director of the Physical Activity and Ethnic Minority Health Laboratory. He has considerable experience in developing physical activity promotion interventions for children and will oversee the recruitment and retention of ethnic minority adolescents and provide his expertise to this project by utilizing mHealth technologies, developing behavioral physical activity promotion strategies and developing physical activity curriculum for children and families.

Robbie Beyl, Ph.D. (Co-I) is Assistant Professor in Biostatistics. Dr. Beyl designed the statistical analyses and power analyses. As a faculty member of the Biostatistics Core at Pennington Biomedical, Dr. Beyl will provide guidance to the Principal Investigator for the randomization schedule and data management, analysis, and interpretation.

The **Project Manager** will provide coordination and oversight of the clinical project including study start-up and IRB regulatory submissions, the creation and testing of manuals of procedures, weekly study meetings to monitor progress in recruitment, enrollment, and data collection at assessment visits and during the intervention. The Project Manager will also provide leadership for intervention staff and will serve as a liaison between the investigators and the data collectors and study staff to help ensure that project milestones are met.

Drs. Staiano and Webster will consult with each other and build consensus on administrative and scientific decisions that must be made during planning and execution of the protocol. During the proposed project, Drs. Staiano and Webster will hold a weekly meeting with the study team, which will be led by Dr. Staiano. Further, Drs. Staiano and Webster will meet alone and occasionally with the Project Manager no less than once every two weeks to review the study status and address administrative tasks. Additional consults will occur on an “as needed” basis. Finally, Dr. Staiano will meet with the intervention team once per week to facilitate treatment fidelity, and Dr. Webster will meet with the data assessment team biweekly to ensure protocol fidelity.

Prior Approvals

The YMCA administrative staff will be required to provide written approval to allow the conduct of study procedures at their site.

Compensation

Subjects will be compensated up to $75 for participation, provided in increments of $25 (upon the completion of the Baseline Visit [Week 0], the End of Treatment Visit [Week 12], and the Follow-up Visit [Week 24]).

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

Participants and participating families will be required to bear the cost of transportation to and from all study visits.

Consent Process

Informed consent will be obtained prior to conducting any study procedures. 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. The study procedures will be explained to parent(s) and prospective participants (3-5 years of age). The parent/legally authorized representative and prospective participant will be asked if they have any questions about the study. The parent/legally authorized representative and prospective participant will be offered a waiting period between informing the prospective participant and obtaining the consent. When the parent/legally authorized representative and prospective participant are both ready, the informed consent process will then proceed as follows:

- 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.

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