#PBRC 2018-041

PLAY: An Intervention to Improve Motor Skills in Young Children

Consent to Participate in a Research Study for Minor

Introduction

- We are researchers from Pennington Biomedical Research Center and LSU.
- This study is sponsored by the National Institutes of Health (NIH).
- We invite your child to participate in a research study that will help us to learn about an intervention delivered through a mobile phone application (app) to parents, with the goal of teaching fundamental motor skills (movement skills) to their preschool-aged children.
- We plan to enroll up to 74 parent/child dyads in this study over a period of 2 years. Your child's expected time in the study will be approximately 7 months.

You and Your Child Can Participate if:

- Your child is currently 3-5 years of age.
- Your child is physically capable of exercise.
- Your child does not score in the 17-20 range or > 129 Gross Motor Index on the Test of Gross Motor Development (TGMD-3)
- Your child has no mobility limitations that impair his/her ability to perform movement skills.
- You have no self-reported mobility limitations that impair your ability to model the movement skills for your child.
- You have a smart phone and are willing to download and use the study app.
- You have no plans to move outside the greater Baton Rouge area during the study period.

Procedures

- You and your child will be asked to attend a total of 4 assessment visits at a local YMCA or another local community venue. Details for each visit are listed below.

Screening Visit (1 hour)

- You will be asked to complete a survey to assess your child's capability for physical activity.
- Your child will be asked to complete a movement skills assessment. Staff will demonstrate how to complete a skill like running, jumping, catching a ball or throwing. Your child will then practice the skill before being assessed. These sessions will be video and audio recorded to make sure we describe your child's movement correctly.
- You will receive an accelerometer (activity monitor) for your child to wear for 7 days and return at the Baseline Visit.
- You will be provided surveys to fill out at home and return at the Baseline Visit.

Baseline Visit, Week 0 (1 hour)

- You and your child will be asked to return to the YMCA or local community venue approximately 2-3 weeks after the screening visit with the activity monitor.
- Your child will be asked to complete body measurements (height, weight, body composition) and a survey.
- You will be asked to complete surveys.
- You will be asked to allow study staff to download the PLAY app onto your smartphone.

- Upon completion of all Baseline assessments, your child will be randomized into one of two study groups, the Fundamental Motor Skill Condition or the Unstructured Physical Activity Condition. The study group you are assigned determines what lessons you will be provided on the PLAY app during the 12-week intervention period.
    - Fundamental Motor Skill Condition
        - If you are assigned to the Fundamental Motor Skill Condition. You will have access to the Fundamental Motor Skill lessons, example videos, and activity breaks to provide structured motor skill teaching time to your child over a 12-week period.
    - Unstructured Physical Activity Condition
        - If you are assigned to the Unstructured Physical Activity (PA) Condition, you will have access to the unstructured PA lessons and free play examples to promote unstructured PA for your child over a 12-week period.

End of Treatment Visit, Week 12 (1 hour)

- You will be provided an accelerometer in the mail approximately 2 weeks prior to this visit for your child to wear for 7 days.
- You and your child will be asked to return to the YMCA or local community venue at the end of the 12-week program with the activity monitor.
- Your child will be asked to complete a survey, body measurements, and a movement skills assessment.
- You will be asked to complete surveys.
- You will not receive any more text notifications on the PLAY app, but you may continue accessing the materials and videos.

Follow-Up Visit, Week 24 (1 hour)

- You and your child will be asked to return to the YMCA or local community venue approximately 12 weeks after the End of Treatment Visit.
- You will be provided an accelerometer in the mail approximately 2 weeks prior to this visit for your child to wear for 7 days and return at the Week 24 visit.
- Your child will be asked to complete a survey, body measurements, and a movement skills assessment.
- You will be asked to complete surveys.
- Study staff will remove the PLAY app from your smartphone. You will not be asked to use the app after the Week 24 assessment visit.

Risks/Benefits

- We have found that there is **no more risk** to the movement skill assessments than during typical play time. In the unlikely event that there is an injury, we will stop the assessments immediately.
- There are no known risks or discomforts to your child during the body measurements.
- Your child may find the activity monitor 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.
- You and your child does not have to answer any survey questions he/she does not want to answer.
- We cannot promise any benefits from your child being in the study; however, your child may experience changes in their movement skills and their levels of physical activity. If your child takes part in this study, he/she may help others in the future.

Payment

- If you agree to participate, we will pay you up to $75.00 upon completion of the study. You will be paid $25.00 upon the completion of assessment visits after enrollment (Week 0, Week 12, and Week 24). Your checks will be requested from the LSU payroll department at each appropriate milestone. It usually takes about 3-4 weeks for the check to arrive at Pennington Biomedical Research Center.

Voluntary Participation

- Your child's participation in this study is completely voluntary.
- If you desire, you may stop the study and withdraw your child from the research at any time and for any reason without penalty to you or your child.
- We know that young children easily become bored or fussy. We will stop the study visit if your child becomes upset.

Confidentiality

- Your child will be assigned an identifying number which will be used throughout the study. Personal identifying information, such as your child's name, will be kept separate from study data and the recordings.
- All data will be stored securely and made available only to persons conducting the study. Every effort will be made to maintain the confidentiality of your study records. However, someone from the Pennington Biomedical Research Center, Louisiana State University, or the NIH (the sponsor) may inspect and/or copy records related to the study.
- Results of the study may be published or used in a future funding application; however, your child's name and other identifying information will remain private. Other than as set forth above, your child's identity will remain confidential unless disclosure is required by law.

Contact Information

- If you have any questions about your child's rights as a research volunteer, you should call the Institutional Review Board Office at (225) 763-2693 or the Executive Director of Pennington Biomedical Research Center at (225) 763-2513.

- If you have any questions about the research study, contact the Principal Investigators, Dr. Amanda Staiano at (225) 763-2729 or Dr. Kip Webster at (225) 578-2923.

Consent

- We will give you a copy of this consent form to keep for your records.
- With your signature, you also acknowledge that you have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

If you are willing for your child to volunteer for this research study, please sign below.

I, (parent/guardian's name) _____, agree to allow my child _____ (child's name) to participate in this research study.
Signature of parent/guardian _____

Today's Date: _____/_____/_____

Child's Date of Birth: _____/_____/_____

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

The study volunteer is a child. I certify that I am his/her legal guardian and legally authorized to enroll him/her in this research study. Misrepresentation of this authority could result in civil and/or criminal penalties.

Amanda Staiano, PhD
Principal Investigator

With this additional signature, I agree to be re-contacted for follow-up information related to this study.

_____
Printed Name of Child

_____ _____
Parent/Legal Guardian Signature Date

Are you interested in receiving information about other Pennington Biomedical Research Center studies?

Check all the apply: Via Mail: ___ Email: ___ Phone: ___

Signature: _____