

Study ID: HUM00133319 IRB: Health Sciences and Behavioral Sciences Date Approved: 9/10/2018



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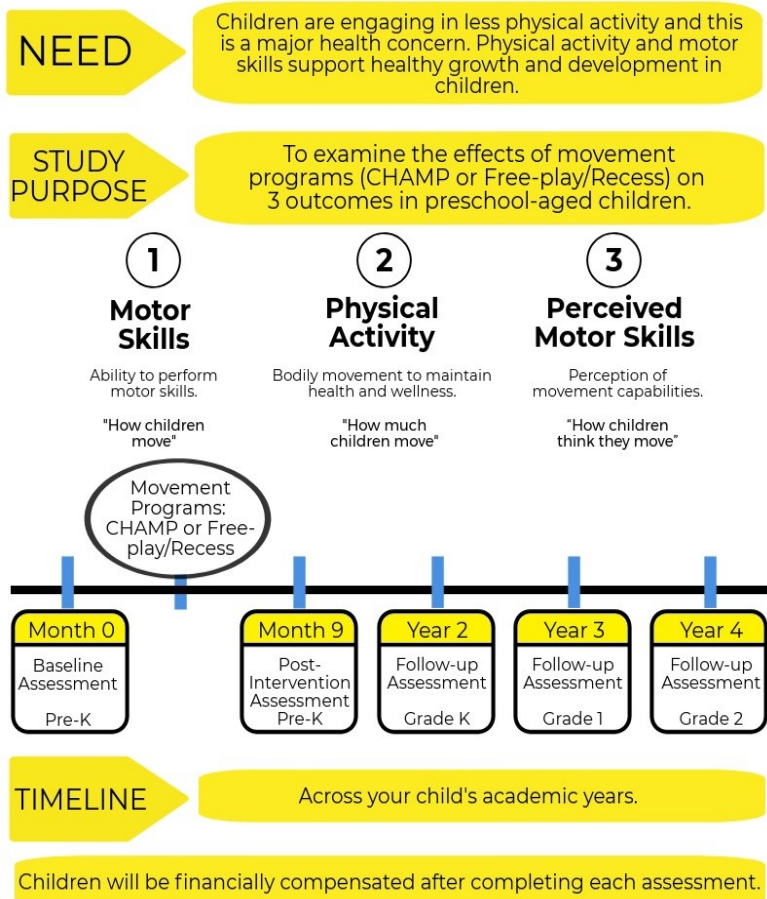
Consent to Participate in a Research Study

Title of the Project: A PATH (Promoting Activity and Trajectories of Health) for Children (Phase I, Cohort 2)

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Alison Miller, Ph.D., University of Michigan, School of Public Health
David Stodden, Ph.D., University of South Carolina, School of Education

Invitation to Participate in a Research Study



We invite your child to participate in a research study funded by the National Institutes of Health that examines the effects of a motor skill intervention on motor skills, perceived motor skills, and physical activity in preschool-aged children, entering Kindergarten the following year.

Study Overview

Preschool classes at Ford, Perry, and Beatty Early Learning Centers will be assigned to 1 of 2 movement programs, the **Children's Health Activity Motor Program (CHAMP)** or **control (normal preschool free-play/recess)** during the **school day**. CHAMP is an evidence-based intervention that teaches motor skills through instruction and hands-on experiences. Classes will be randomly assigned (e.g., a flip of a coin and there is an equal chance to be in either

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movement program). The movement programs will last for an entire school year (4, 30-minute classes a week or 3, 40-minute classes a week, based on the needs of the school schedule). If you agree to have your child participate in the study, we will assess their: **motor skills, physical activity, and perceived motor skills** prior to the start of the program, during, immediately following the program, and for 3 years after the study (during Kindergarten, 1st, and 2nd grade). All tests, except for physical activity, will be collected in small groups during the school day.

These measures will be assessed for the study:

1. **Motor skills** will be measured with the Test of Gross Motor Development to assess your child's performance in the following skills: run, skip, jump, hop, leap, gallop, slide, roll, throw, catch, strike, bounce/dribble, and kick. Dr. Ulrich, one of the co-investigators on the study, developed this test. We will also measure his/her kicking and throwing velocity, running speed, hopping and jumping distance, and successful catching attempts. Motor skills assessments require us to video record your child's performance. These videos will be viewed and scored at a later time by researchers in a secured lab.
2. **Physical activity** will be measured with an accelerometer called an Actigraph. An Actigraph is a small, lightweight water-resistant device that will be attached to your child's wrist (non-writing hand) for 7 days. The monitor records the amount of time your child spends in physical activity. Parents are not financially responsible for devices that are not returned (lost) or broken, but attempts will be made to find the lost device. If a device is not returned children will not participate in the future rounds of physical activity monitoring.
3. **Perceived motor skills** will be measured with the a) Harter and Pike Pictorial Scale of Perceived Motor Competence and Social Acceptance and the b) Perceived Fundamental Motor Skill Competence Video-based Scale. For both assessments, children will see 2 static pictures and/or video clips of a child engaged in motor-related task; one image shows a highly competent/skilled child and the other image shows a not as highly competent/skilled child. The child is asked to select the image that most resembles them.
4. **Family Questionnaire**. During the consenting process, you will be asked to complete a family questionnaire to provide us with some additional information regarding the home environment, family structure, physical activity behaviors, sleeping behaviors, and screen time habits that could help to inform our findings. Fully completed questionnaires will be entered in a drawing to win one of eight \$50.00 Gift Cards to Wal-Mart.
5. **Body composition**. Your child will stand on a standard height and weight scale to measure their height and weight. Waist circumference will be assessed with a non-elastic plastic tape measure that will be placed around your child's waist in a standing position.

Parents will receive a yearly report regarding their child's assessment findings.

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Benefits of Participation

Although your child may not directly benefit from being in this study, others may benefit because findings will contribute to science and answer novel questions linking motor skills to physical activity.

Risks and Discomforts of Participation

We have taken steps to minimize any risks for the study. Risks include common play injuries that young children might experience when playing on a playground or outside.

Compensation for Participation

For your child's participation in this research project, he/she will receive an incentive upon the return of the device at each assessment period across the length of the study: a choice of a \$10.00 gift card or \$10.00 worth of incentives (i.e., gifts/prizes). To compensate the parent/guardian for their time, you will receive a one-time \$5.00 cash incentive for completing this informed consent. Completed Family Questionnaires will be entered into a drawing to win 1 of eight (8) \$50.00 gift cards to Wal-Mart (i.e., 4 for each school). 2, \$50 gift card drawings will occur each day (i.e., 1 for each preschool) and will occur over 4 consecutive days. Early withdrawal from this study will forfeit future compensation.

Confidentiality

Findings will be published from this study and will not include any information that would identify your child. Data from this study will be used for educational and research purposes, and children's performance/responses will be reported as group results. Your child's privacy will be protected and all records will be confidential. To preserve confidentiality, all children will receive an identification number for data collection purposes. However, video data (i.e., digital recordings) could result in a potential breach of confidentiality. Data will only be reviewed by the research team and stored on university-secured password protected computers at the University of Michigan and University of South Carolina. The research team at the University of South Carolina will review limited motor skills data (i.e., kicking and throwing velocity, running speed, hopping and jumping distance, and successful catching attempts) on university-secured password protected computers.

Storage and Future Use of Data

Data will be stored on university-secured password protected computers and kept in a locked file cabinet located in a key code access laboratory (Child Movement, Activity, and Developmental Health Lab) in Central Campus Recreation Building 1271C. Limited motor skills data will be stored on encrypted computers at the University of South Carolina. **All data will be retained for future research use and we will re-contact you to complete follow-up assessments on your child during Kindergarten, Grade 1, and Grade 2.**

Voluntary Nature of the Study

Participating in this study is completely voluntary. Even if you/your child decide to participate now, you/your child may change your mind and stop at any time. Your decision whether or not to allow your child to participate

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will not jeopardize his/her future relationship with the University of Michigan, the School of Kinesiology, or his/her current educational institution. If you decide to withdraw before this study is completed, your child's data will still be used.

Contact Information for the Study Team

If you have questions about this study (e.g., including questions about scheduling or your compensation for participating), please contact the Child Movement, Activity, and Developmental Health Laboratory at cmahlab.umich@gmail.com (email) or 734 615-5155 (office), or the Lab Director, Dr. Leah Robinson, at lerobin@umich.edu (email) and 734-647-7645 (office).

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board, 2800 Plymouth Rd., Bldg. 520, Room 1169, Ann Arbor, MI 48109-2800, (734) 936-0933, irbhsbs@umich.edu.

Clinical Trial

This study is registered as a Clinical Trial and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. However, no individually identifiable data is included in the registration or results reporting. A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U. S. Law. This website will not include information that can identify you *or your child*. At most, the website will include a summary of the results.

The registered Clinical Trial is # NCT03189862.

PLEASE PROCEED TO THE NEXT PAGE FOR CONSENTING PROCESS ITEMS.

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Consent

By signing this document, you are agreeing for your child to be in the study. You will be given a copy of this document for your records. Be sure that we have answered any questions you have about the study and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

I agree to allow my child to participate in the study.

Printed Name

Signature

Date

Please provide the following information.

- a) **Your child's name (printed):** _____
- b) **Your child's date of birth: (Month)** _____ **(Date)** _____ **(Year)** _____
- c) **Your child's sex and race/ethnicity:** _____ **(Sex)** _____ **(Race/Ethnicity)**
- d) **Would your child like to receive a \$10 gift card** ☐ **or \$10 in incentives** ☐ **(check one)?**
- e) **Your physical/mailling address for compensation:** _____.
- f) **Parental email and phone number for reminders regarding Actigraph (physical activity) monitors.**
 _____ **(email)** _____ **(mobile #)** _____ **(home #).**

I _____ **(Parent/Guardian Name) agree to provide my address and phone number.**

Signature

Date

OPTIONAL CONSENTING ITEMS

We request additional consent on the following items below. These items are optional.

a) Consent to be Photographed.

I agree to allow my child to be photographed and understand that the photographs may be used for educational, research, and or publicity purposes.

YES _____ **NO** _____

_____ (your signature)

b) Consent to be Contacted for Participation in Future Research.

I agree to be contacted for participation in future research.

YES _____ **NO** _____

_____ (your signature)

THANK YOU FOR YOUR COOPERATION!