**Official Title: A PATH (Promoting Activity and Trajectories of Health) for Children**

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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)

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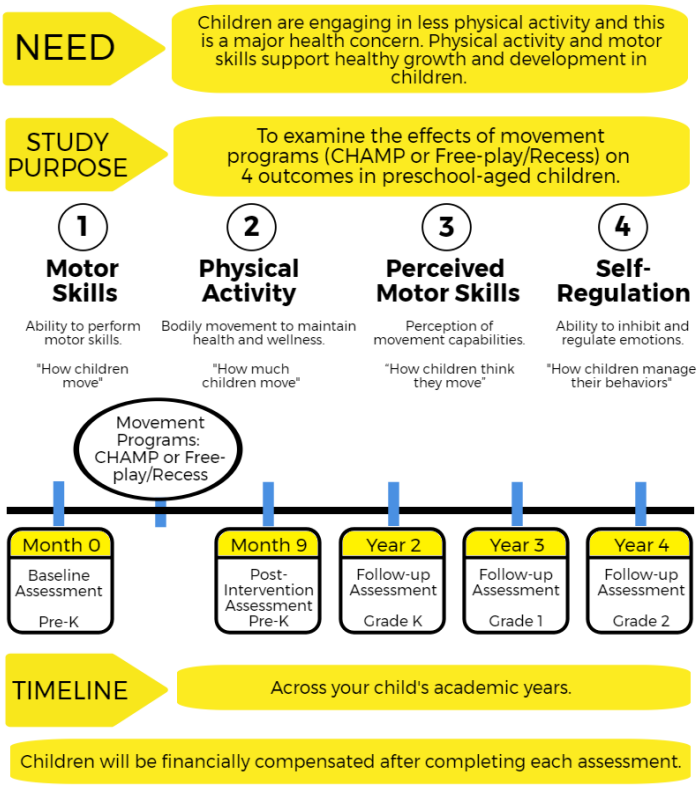
## Invitation to Participate in a Research Study

We invite your child to participate in a research study funded by the National Institutes of Health that examine 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 and Perry Early Learning Center will be assigned to 1 of 2 movement programs, the **Children's Health Activity Motor Program (CHAMP)** or a **control (normal preschool free-play/recess) during the school day.** The movement programs will last for an entire school year (30 minutes/4 days per week). If you agree to have your child participate in the study. We will assess their: **motor skills, physical activity, perceived motor skills, self-regulation** prior to the start of the program, 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 over 4 days and will last less than 30 minutes.

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. We will also measure his/her kicking and throwing velocity, running speed, and hopping & jumping distance, and successful catching attempts. Motor skills assessments require us to video record your child's performance that 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 round 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 two (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 a highly competent/skilled child. This child is asked to select the image that most resembles them.
4. **Self-regulation** will be assessed using a) recognition task (i.e. "Mr. Ant") b) card sorting task (i.e. "Rabbits and Boats") where your child will recall and sort information that is seen on an iPad screen. These tasks are computerized and completed on an iPad. c) the Head-Toes-Knees-Shoulder Task (HTKS) where your child will learn and remember a rule to a game and apply it one way, then re-apply that rule in a new way. The HTKS requires video recording and will be scored at a later date by researchers in a secured lab. d) Your child's classroom teacher will complete an assessments of your child's interactions and behaviors with their friends in the classroom.
5. **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 or Kroger Shopping Center.
6. **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.

## 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. Risk 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 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 in a drawing to win one (1) of eight (8) $50.00 gift cards to Wal-Mart or Kroger Shopping Center (i.e., 4 for each school). Two (2), $50 gift card drawings will occur each day (i.e., one (1) for each preschool) and will occur over four (4) consecutive days. ID numbers of completed surveys will enter four discrete pools on each day of the drawing (e.g. Subjects 1-37 on Day One for each site, Subjects 38 - 75 on Day Two for each site,), and Subjects 76-113 on Day Three for each site, Subjects 114-150 on Day 4 for each site). Parents will receive a yearly report regarding their child's assessment findings. 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. Video data will only be reviewed by the research team and stored on a university-secured password protected computer.

## Storage and Future Use of Data

Data will be store data 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 CCRB 1271D. **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.** Hard copy of data will be shredded will be deleted 5 years after the completion of the study.

## 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 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 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 trial is registered 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 Web site will not include information that can identify you *or your child*. At most, the Web site will include a summary of the results.

The registered Clinical Trial # NCT03189862.

***PLEASE PROCEED TO THE NEXT PAGE FOR CONSENTING PROCESS ITEMS.***

**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 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/mailing address for compensation: _____.**

f) **Parental email and phone number for reminders regarding actigraph (physical activity) monitors.**

**_____ (email) _____(mobile #) _____ (home #).**

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

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**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 be photographed and understand that the photographs maybe use for* educational, research, and or publicity purposes. ***YES_____*** ***NO_____***

_____

Signature

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

*I agree to be contacted for participation in future research.* ***YES_____*** ***NO_____***

_____

**THANK YOU FOR YOUR COOPERATION!**

## Statistical Analysis Plan

*Analyses of primary outcomes*

Before conducting outcome analysis, we will examine the range and frequency distributions for all variables and will transform variables when appropriate. Preliminary analyses will assess each outcome cross-sectionally at baseline and at all follow-up time points. We will compare study groups (ie, CHAMP vs Control) for comparability and change in variables over time. To study both the short-term (immediate) and long-term (sustainable) effects of CHAMP, we will assess all longitudinal outcomes by both summary statistics and descriptive data figures over the baseline, post-intervention and the start and end of the academic year during Years 2, 3 and 4. Since the samples will be collected in different classrooms and different preschools, our data will have a clustered structure, which means within-cluster correlations likely exist.

For such clustered longitudinal data, we will use primarily random effects in the following models to account for multilevel correlations among the measurements: Mixed Model Regression, Growth Curve Modelling and Structural Equation Modelling.[93–96] Random effects are appealing here to account for some latent mediating factors that may exist in the study. We will use the Mixed Model Regression to determine the effects of our proposed intervention on primary and secondary outcomes (Aim 1 and 2). Growth Curve Models will be used to understand if, and how, time-course changes in motor performance, perceived physical competence and physical activity differ between the intervention and control groups and Structural Equation Modelling for mediation analysis (Aim 3).

More specifically, in Aim 1, the immediate post-intervention effect of CHAMP (compared with control participants) on each outcome variable will be evaluated at post-intervention (Month 9). We will examine descriptive statistics on both pre-intervention and post-intervention measures of the outcome variables for each group. The change in motor performance, perceived physical competence and physical activity (ie, physical activity refers to time spent in MVPA) will be compared between two groups using regression models, adjusting for other confounding factors (eg, age and sex). Random effects will be included in the model to accommodate the potential within-cluster correlation coming from the nature of how the data are collected. We will investigate the amount of attrition from pre-intervention to post-intervention, and attempt to identify the baseline predictors of the likelihood of dropping out (as an indication of possible bias in the change estimates).

In Aim 2, we will use Mixed Model Regression to analyse the clustered longitudinal data from our RCT to assess the long-term effects of the CHAMP intervention on improving the three outcome measures: motor performance, perceived physical competence and physical activity. In this analysis, we can obtain the estimates of the long-term longitudinal intervention effect by adjusting for confounding factors that include sex and age. For physical activity and BMI, we will test for a possible delay before any significant change because of the difficulty of achieving health behaviour change by adding time-lagged covariates related to behaviour changes in the regression analysis. We will also conduct exploratory analyses to test interaction effects to understand potential modified intervention effects by different levels of behaviour changes. The intervention is designed to promote a positive trajectory of children's motor performance, perceived physical competence, and physical activity, and we will specifically test interactions between intervention and time and between baseline motor skills, perceived physical competence, and time to see which baseline measure is a stronger driver of increasing physical activity.

In Aim 3, we will apply the Growth Curve Models to understand if, and how, time-course changes in motor performance, perceived physical competence and physical activity differ between the intervention and control groups. This model is also used to determine a time

window over which the intervention effect appears stronger. We will use Structural Equation Models to determine which hypothesised constructs might be responsible for the intervention effect on longitudinal physical activity. Based on the results of our previous work, for example, we hypothesise that perceived physical competence will not mediate the relationship between motor performance and physical activity at baseline, but perceived physical competence will mediate the relationship between motor performance and physical activity immediately post-intervention and across the 3-year follow-up period. We will use Mplus software to fit Structural Equation Models, and the goodness of fit of Structural Equation Models will be assessed using multiple criteria such as $\chi^2$ to df ratio (<2) and the root mean square error of approximation (<0.05).

Our goal is to have limited missing data but there is a potential for missing data. Assuming that data are missing at random, multiple imputation techniques will be used to replace missing data.[97] Missing data will be assumed to be missing at random if no participant demographics or primary outcomes are correlated with missingness. Mixed-effects models allow for partial information to be included for individuals who may dropout before any post-intervention data collection periods. Missing values will be multiply imputed using available covariates by sequential imputation. This approach allows optimal use of the available data in analysis involving change measures.

***Data management***

Extreme care to ensure high-quality and secure data will be exercised. All data will be stored securely at the University of Michigan and partial data (product measures) at the University of South Carolina. All data will have only a numerical identifier so that individual respondents, except for video data, cannot be identified. All data will be reported as aggregate statistics and no individuals will be recognisable from the data reported. All data will be perused for consistency, errors of omission and appropriateness of the response. Once a coded and cleaned data file has been prepared, frequency distributions and descriptive statistics (means, SD and ranges) for each of the measured variables will be used for consistency checks and to verify the comparability of the groups. Logic check programmes will be run to ensure that each data point falls within the expected range or corresponds to possible values in the codebook. These tracking system files will be maintained on a secure server at the University of Michigan. Data will be analysed using SAS 9.3.[97 98] All members of the study team will be required to complete the web-based National Institutes of Health University of Michigan Responsible Conduct of Research training programme. The investigative team will engage in the ongoing data management training, data monitoring and measurement training throughout the investigation.

## Statistical Analysis Plans, Power considerations, and Data management for Self-regulation measures (Supplemental Award)

*Overall Analysis Plans.* We will apply transformations to assure normality, run descriptive statistics, and assess potential covariates to include. While maximum effort will be made to retain all participants and minimize the amount of missing data, we anticipate there will be some data lost-to-follow-up and incomplete measures. Therefore, we will address missing data in the analysis plan by applying advanced statistical techniques, such as “multiple imputations” using PROC MI in SAS and IVEWARE SAS macro. Our overall approach will be to employ multivariate analysis to assess associations among key variables using the appropriate models based on the distribution of the data (i.e., normal, categorical data, count data, reaction time data). Since this is a cluster-randomized trial, adjusting the covariates (e.g., child sex, age, race/ethnicity) will aid in controlling additional unbalancesess due to the limited sample size. All analysis will be done using SAS 9.3 or R 4.1.0[96-98]. Additionally, we will perform “intent to treat”

analysis and assume all subjects comply to the assigned group. Findings/results from the study will also following the CONSORT guidelines.

*Power considerations.* When we calculate the sample size and power, we assumed the intra-cluster correlation is 0.3. The achievable power is calculated for a detectable effect size, which is the detectable mean difference standardized by the square root of sample variance. Given the randomization design with 70 children in the intervention group and 50 children in the control group, we have 80% power to detect a difference in cognitive SR, behavioral SR, or emotional SR with an effect size of 0.52 and a Type I error level of 0.05.

*Specific analysis plan for Aim 1.* Examine the immediate (pre- to post-test) intervention effects of CHAMP (compared to control participants) on cognitive SR (cognitive flexibility, working memory, attention shifting), behavioral SR (behavioral inhibition), and emotional SR (emotion regulation). The immediate post-intervention effect of CHAMP (compared to control participants) on each SR outcome variable will be evaluated at post-intervention. We will examine descriptive statistics for both pre-and post-intervention SR outcome variables for each group. The change in cognitive SR, behavioral SR, and emotional SR scores will be compared between the intervention (CHAMP) and control groups using regression models, adjusting for other confounding factors. We assume randomization will be successful and we will monitor throughout the trial. It is always good practice to monitor along the way and we will do so, but randomization may be imperfect as this is a randomized cluster trial taking place in the real word (i.e., Head Start setting). If randomization does not work this will lead to biased results and methodology, our planned analyses to adjust other variables will be considered. Random effects will be included in the model to accommodate for the potential within-cluster correlations due to nested classroom data. We anticipate that some children will have only partial adherence to the intervention (i.e., attend a subset of sessions), thus we will also conduct a dose-response analysis where dose corresponds to number of sessions. We will investigate the amount of attrition from pre-to post-intervention, and attempt to identify baseline (or pre-intervention) predictors of dropping out. The information will indicate possible bias in the change estimates.

*Specific analysis plan for Aim 2.* Examine the associations between SR (cognitive SR, behavioral SR, and emotional SR) and changes in health behaviors (motor competence, perceived competence, physical activity) and health outcomes (body mass index, waist circumference). We will further evaluate the associations between changes in SR and changes in children's health behaviors and outcomes, using regression models. More specifically, we will examine the strength of association between each SR variable and our outcomes of interest using bivariate analyses to compare change in SR to change in motor competence, perceived competence, and PA (using an alpha value of $p<.05$). To test whether the strength of association varies by intervention status, we will use multivariate regression models (controlling for covariates as needed) to examine the association of SR and outcomes in each group (CHAMP and control). Similarly, random effects will be included in the model to accommodate for the potential within-cluster correlations from nested classroom data. We will further apply Structural Equation Models (SEM) to evaluate whether the CHAMP intervention has a causal effect on children's health outcomes mediated through SR.

*Data Management.* Extreme care to ensure high-quality and secure data will be exercised. All data will be stored securely at the University of Michigan. All data will have only a numerical identifier so that individual respondents, except for video data, cannot be identified. All data will be reported as aggregate statistics and no individuals will be recognizable from the data reported. All data will be scanned for consistency, errors of omission, and appropriateness of the response, and 30% of data will be checked by a blinded member of the research team. Once a coded and cleaned data file has been prepared, frequency distributions and descriptive

statistics (means, standard deviations, and ranges) for each of the measured variables will be used for consistency checks and to verify the comparability of the groups. Logic check programs will be run to ensure that each data point falls within the expected range or corresponds to possible values in the codebook. These tracking system files will be maintained on a secure server at the University of Michigan. Data will be analyzed using SAS 9.3 or R 4.1.0 [96-99]. All members of the study team will be required to complete the web-based National Institutes of Health University of Michigan Responsible Conduct of Research Training Program. The investigative team will engage in ongoing data management training, data monitoring, and measurement training over the course of the investigation. Rewards and incentives will be incorporated after each assessment time point to aid in participant engagement.