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

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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 χ^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.