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Study protocol for testing the association between physical activity and academic outcomes utilizing a cluster-randomized trial

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ABSTRACT

The Physical Activity Guidelines for Americans recommend adolescents engaging in 60 min of physical activity (PA) every day. Students should spend at least 30 min being active while at school. However, schools rarely provide that much PA time for students. This paper describes the planned analyses for a study evaluating the relationships between PA (measured as average daily minutes of Moderate to Vigorous Physical Activity [MVPA]) and educational outcomes of standardized test scores and classroom grades cross-sectionally in 4 th grade and longitudinally from 4 th to 5 th grade. Investigations of moderators (both student- and school-level), mediators, and potential dosage of average MVPA thresholds are outlined. To ensure a high level of variability in student PA, the Health Empowers You! program is implemented in a random sample of half of the participating schools. The intervention is designed to affect students' PA behaviors and health outcomes (cardiorespiratory fitness, body mass index). Utilizing accelerometer data from students in participating schools, the relationship between PA and health and academic outcomes (academic achievement test scores, reading lexile, grades, attendance, and tardiness) is evaluated. A total of 4968 grade 4 students across 40 schools (20 receiving intervention) participated (75% participation rate), and this cohort is being tracked from grade 4 through grade 5. In addition, implementation process and fidelity data are gathered. Given that school closures in response to COVID-19 pre-maturely terminated Spring 5 th grade data collection, modifications to the original analysis plan are discussed throughout.

1. Introduction

As noted in the Physical Activity Guidelines for Americans [1,2], physical activity (PA) has a myriad of physical and mental health benefits. Consistently meeting the recommendations to engage in 60 min of daily PA is associated with better weight outcomes, improved fitness, reduced risk of cancer and heart disease, and decreased anxiety and depression [2]. However, most US children and adolescents are insufficiently active [3]. Because children typically spend much of their day at school, ensuring that schools offer students regular opportunities to engage in PA is crucial [4], and it is recommended that children engage in at least 30 of their 60 daily minutes of PA while at school [4,5]. Although academic outcomes are a primary focus for schools, research increasingly suggests that PA can benefit academic outcomes, highlighting the importance of practices to support students' health [6]. In 2015, the Every Student Succeeds Act [7] required schools to consider multiple aspects of student success, expanding school accountability measures to include a focus on "non-academic indicators." Some states now include physical fitness or other health indicators as accountability measures [8,9].

Strategies to promote PA can span a wide array of activities, but generally fall into three approaches: physical education (PE), opportunities for PA during school hours other than PE class, and PA opportunities before or after school. Together, these three strategies—combined with staff involvement and family and community engagement—make up a comprehensive school physical activity program (CSPAP) [10,11]. Several national organizations recommend that schools develop and implement a CSPAP that allows students to engage in at least 30 min of

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daily [10,11]. However, while 30 min is a pragmatic recommendation, it is unclear what 'dose' of PA is required to promote improved academic outcomes. In fact, there remain many questions about the impact of PA on academic outcomes.

In 2010, the US Centers for Disease Control and Prevention reviewed 50 studies that examined the association between PA and academics, concluding that increasing or maintaining time for PA at school might improve educational outcomes, but that more studies are needed [6]. The ability to draw definitive conclusions was limited due to a lack of studies utilizing rigorous research methods such as randomized controlled trials (RCTs) [8]. A systematic review in 2018 identified only seven high-quality trials that assessed the impact of PA on academic outcomes; the authors concluded that there is strong evidence for beneficial effects of PA on math achievement, but equivocal evidence for improved overall academic performance [12]. That study utilized an expert panel to identify priorities for the most important future research on this topic, which included examination of mechanistic questions such as moderators of the relationship between PA and academics. Thus, although several RCTs have already been conducted on this topic, there remains a need for long-term, rigorous, evaluations that examine the mechanisms through which PA may improve academic outcomes.

2. Materials and methods

2.1. Project aims and objectives

The overall aim of this study is to evaluate the relationship between PA and academic outcomes. This is done in conjunction with the implementation of *Health Empowers You!* a school-based PA intervention, randomly assigned to half of the participating schools. The intervention is designed to change school PA practices, allowing students to engage in at least 45 min of PA during the school day. The purpose of implementing *Health Empowers You!* is not so that the intervention may be evaluated; instead, the purpose of implementing the intervention is to yield a wider range of observed student PA. To gain reliable estimates of the relationship between PA and the educational outcomes of interest, particularly at the extremes of PA, the full range of PA levels needs to be observed among students in the sample. Since student PA in schools is typically limited [13], implementation of *Health Empowers You!* will produce a wider, well-represented range of student PA.

The objectives of the study span both short-term and long-term outcomes in the investigation of the relationship between PA and academic outcomes. Therefore, the following objectives will be analyzed with outcomes cross-sectionally and longitudinally.

Specific objectives include

1: to examine the relationship between student PA and academic outcomes;
2: to examine mechanisms through which such improvement may occur (i.e., the existence of potential mediating relationships), by specifically evaluating:
  2.1: whether PA is associated with physical fitness, Body Mass Index (BMI) and proximal behavioral outcomes such as attendance and tardiness;
  2.2: whether student PA, physical fitness, Body Mass Index (BMI) and proximal behavioral outcomes are associated with academic outcomes;
  2.3: whether mediators of the relationship between PA and academic outcomes exist utilizing the relationships identified in 2.1 and 2.2
3: to determine whether student-level characteristics and school-level characteristics moderate the relationship between student PA and academic outcomes
4: evaluate the existence of a relationship between changes in PA and changes in student academic outcomes between 4th and 5th grade, and
5: to identify what amount of PA time is needed to see improvements in academic outcomes.

The study is led by a team at Emory University, with collaborators at HealthMPowers (Norcross, GA) and Boise State University. The research protocol was approved by the Institutional Review Board at Emory University and also by the collaborating school district. The multidisciplinary team includes researchers with expertise in epidemiology, health education, statistics, psychology, education, and PA. The delivery of the intervention is led by HealthMPowers, an organization that was founded by the US Centers for Disease Control and Prevention, Emory University, and Children's Healthcare of Atlanta. Over the past decade, HealthMPowers has provided expert technical assistance to more than 2000 schools in Georgia to implement fitness testing and other PA promotion programs. This research study is also guided by an expert advisory panel that includes 10 nationally-recognized experts in education, PA, methodology, and other key aspects of the project.

The original plan for meeting study objectives included data collection on student outcomes through the end of the 2019–2020 school year. However, the participating school district closed their brick-and-mortar operations for much of the Spring 2020 school year, and no standardized assessments were administered. Modifications to the focal outcomes in the longitudinal objectives were made accordingly. These modifications are further discussed when measures are presented in section 2.8.

2.2. Study design

The study utilizes a two-arm cluster-randomized design, with 20 schools assigned to intervention condition and 20 assigned to the delayed-intervention control condition. A total of 40 schools were recruited for the project, from within one large school district in the metropolitan Atlanta area. Data will be gathered over three school years (2017-18, 2018-19, and 2019-20).

2.3. School recruitment and randomization to condition

The first step was determination of eligibility. With the assistance of collaborators at the school district, demographics for all elementary schools in the district were obtained, including: number of grade 3 classes; average number of students per grade 3 class; racial/ethnic composition of the student body; and the economic make-up of the students' families, which was proxied by the percentage of students at each school who were eligible for free or reduced-priced meals (FRPM). In addition, because PE is a major source of PA time at school, efforts were made to account for PE minutes in the randomization. School district administrators provided the researchers with information about the scheduling of PE classes at each school. This was used to calculate the number of minutes of PE that each school provided per month, on average, to grade 4 students.

The first step in school selection was to identify 40 schools to approach for participation. Two strata were created to ensure that higher and lower socioeconomic schools were sampled. Schools were allocated to one of two groups: higher socioeconomic status (less than 50% FRPM), and lower socioeconomic status (50% FRPM or more). Within each group, a random number generator was used to assign each school a number, the list was sorted, and the first 20 schools were selected. The demographics of these 20 schools were comparable to the demographics of all schools within the strata, indicating that the 20 selected were representative of that strata. These schools were then randomized to condition.

The randomization was conducted by a PhD level educational methodologist. An urn procedure was used, which adjusted the probabilities of allocation based on two key school-level characteristics: socioeconomic status (based on FRPM), and the number of minutes of PE per month scheduled for grade 4 students. After the allocation of 20 schools to the intervention and 20 schools to the delayed-intervention

control, comparisons of the demographic characteristics of both groups (number of students, number of grade 4 classrooms, racial/ethnic composition, FRPM, PE minutes) were made. This confirmed that there were no statistically significant differences between the characteristics of the schools in each of the two conditions. All 40 schools accepted the condition randomization and agreed to participate in the project.

2.4. Student recruitment

All students who were not enrolled in a full-time special education classroom in grade four at participating schools at the beginning of the 2018-19 school year were eligible for enrollment in the study. Teachers of special education classrooms were allowed to participate in training and received resources for implementation at their discretion; however, given that these classes typically include multiple grade levels and may require complex additional supports, students in these classes were excluded from data collection. The recruitment process was facilitated by the principal and office staff at all of the schools participating in the study, with information distributed to parents in August 2018. Enrollment into the study included providing parental consent and student assent for participation in the PA measurement (accelerometry), and providing authorization for the school district to share and link archival records (test scores, reading lexile, grades, attendance, and tardiness) as part of the analytic dataset that the district will provide to the research team each year. A total of 4968 students consented to be in the study. This represented a 75% response rate among all potential eligible students (73% at control schools; 78% at intervention schools).

2.5. Intervention description

Health Empowers You! is a multi-level intervention designed to promote school-wide systems-change to shift school practices and culture, and to promote implementation of a CSPAP that provides students with at least 45 min of PA each day. The intervention has been shown to significantly increase PA levels of elementary school students [14]. Because of its comprehensive, ecological nature and its focus on the whole student, this program is consistent with the Whole School, Whole Child, Whole Community framework [15,16]. This framework focuses on the entire school, leveraging internal resources as well as community resources such as technical assistance and support from health educators.

Trained Physical Activity Specialists (PASs) provide training and technical assistance to teachers to implement the PA intervention. Teachers are given web content, weekly calendars with PA resources and strategies, monthly training webinars, and exercise equipment to support this content. Four key strategies are used by HealthMPowers to support schools in implementing practices and policies that create a school environment that supports student PA. These include: 1) school engagement and assessment; 2) training; 3) PA equipment and resources; and 4) ongoing assessment and technical assistance. Each of these intervention components are described in more detail below.

2.5.1. School engagement and assessment

In this aspect of the intervention, baseline information was collected about current practices and training was provided for classroom teachers to develop the capacity to increase PA through a school-level action plan. Top-down support was gained by engaging administrators and obtaining their buy-in; teacher accountability was secured by a participation agreement outlining all responsibilities that were expected of teachers in order to receive their stipend at the end of each year. Environmental cues were posted throughout the school to promote PA engagement.

2.5.2. Training and action planning

Classroom teachers were provided with ongoing in-person and virtual training and technical assistance, and PE teachers received professional development to learn and develop strategies to increase physically-active time during PE. In August 2018, the HealthMPowers team trained 4th grade teachers from the intervention schools on strategies and resources for integrating a minimum of 45 min of PA during the school day. A second training for 5th grade teachers occurred in August of 2019. Throughout the two years of the intervention period, school staff received continued training and support from PASs to monitor student PA time and ensure 45 min of daily PA for students using the equipment, resources, and strategies provided.

2.5.3. PA equipment and resources

After the August training, schools were provided with PA equipment, resources and teaching aids aligned to the Georgia Standards of Excellence to facilitate the integration of PA into the school day. Resources included: posters that teach and encourage classroom-based exercises; student commitment pledge cards; web-based resources including short exercise sequences that students and staff could do at their desks without equipment or teacher training; workbooks with weekly calendars of specific physical activities; integrated math and physical activity ideas; and sets of PA equipment.

2.5.4. Ongoing assessment and technical assistance

Objective student PA data were collected via accelerometry at all schools, but in the intervention condition, summary information about student PA was provided to the school team for use in identifying opportunities for ensuring additional PA. This objective feedback allowed PASs to provide additional technical assistance for classroom teachers with low student PA levels, in the intervention condition only. Short (10 min) interactive webinars refreshed teachers on previous content and provided more detailed implementation support.

2.6. Delayed-intervention control condition

In control schools, teachers received a small stipend to facilitate student-level PA data collection over the two-year study period, but they did not receive the intervention. All measures, except those to assess intervention fidelity, were collected from control schools. Control schools received the intervention after the end of the trial, in the fall of 2020.

2.7. Data collection

Data collection for this study leverages the standard accountability measures and assessments that are collected by the collaborating school district (student demographics and academic outcomes), plus additional assessments for this project. Data collection time points and measures are specified in Table 1 and described below.

2.8. Measures

2.8.1. Student-level measures

2.8.1.1. Demographics. At baseline, student age, gender, race/ethnicity, and eligibility for FRPM were obtained from the school district office. The student assent form and parent assent form provided authorization for the school district to share this information with the research team, but student identity (private identifying information) remained protected.

2.8.1.2. Academic outcomes: achievement. The original plan was to use the standardized Georgia Milestone test for reading and mathematics as academic outcomes. The Georgia Milestone's comprehensive summative assessment is administered annually in the spring for each student in grades 3 to 8. The test was first used in Spring 2015 and is the best objective universal indicator of students' academic performance in

Table 1
Student, classroom/teacher and school-level data collection measures and timepoints.

	Spring 2018	Fall 2018	Spring 2019	Fall 2019	Spring 2020
Student Measures					
Demographics	X				
Academic Measures					
Standardized Achievement Test (Georgia Milestones)	X		X		X
Reading Lexile Level	X		X		X
Grades		X	X	X	X
Attendance	X		X		X
Tardiness	X		X		X
Physical Activity					
5-day accelerometry during the school day		X	X	X	X
Teacher Quarterly PA Reporting Form		X	X	X	X
Student Anthropometric Data from FitnessGram					
Cardiorespiratory Fitness (PACER test)	X	X	X	X	X
Body Mass Index	X	X	X	X	X
Classroom/Teacher Measures					
Teacher Survey (knowledge, attitudes, practices)		X	X	X	X
School Measures					
Demographics	X				
PA Practices and Policies Survey		X		X	
Observational School Environment Checklist		X		X	

Note. Spring 2018 is the students' 3rd grade, Fall 2018 and Spring 2019 are the students' 4th grade, and Fall 2019 and Spring 2020 are the students' 5th grade. Many of the assessments planned for Spring 2020 could not be collected, e.g., standardized achievement tests, whereas others were only recorded for a portion of the sample, e.g., 5-day accelerometry.

Georgia. Georgia Milestones measures how well students have learned the knowledge and skills outlined in the state-adopted content Standards of Excellence. However, given the precautions taken with regard to COVID-19 resulting in school closures across the state of Georgia, 5th grade standardized test scores were unavailable whereas 4th grade standardized test scores were still available. Therefore, the academic achievement outcomes of interest for students in 4th grade are standardized test scores and teacher-assigned grades and for students when in 5th grade are only teacher-assigned grades. Class grades in the district are determined by classroom specific assessments (50%; e.g., teacher created formative assessments), summative assessments (40%; either teacher developed or from specific curriculum assessments), and district standardized tests (10%). Though classroom grades are not standardized and validated in the same manner as state-wide assessments, classroom grades have been shown to predict outcomes of interest such as high school completion [17] and college outcomes [18] and therefore are important outcomes in education research. Understanding the factors that may predict or affect growth in student grades is relevant for improving these long-term outcomes.

2.8.1.3. Academic outcomes: reading lexile. Reading Lexile level is a method to measure a student reader's ability. Initially, students' Lexile level were to be provided by the district each year, with calculation of student growth curves to compare changes over time. However, due to school closures in response to COVID-19, reading Lexile scores will be available only for 4th grade.

2.8.1.4. Academic outcomes: attendance/absenteeism. The number of days a student was absent from school for the school year. This information was available only for the entire school year and not by semester. Attendance data were provided to the district from each school for each student. Information for students in participating schools were then provided by the district for analyses.

2.8.1.5. Academic outcomes: tardiness. The number of days a student was tardy to school for the school year. This information was available only for the entire school year and not by semester. Tardiness data were provided to the district from each school for each student. Information for students in participating schools were then provided by the district for analyses.

2.8.1.6. Secondary outcomes: cardiorespiratory fitness and body mass index. FitnessGram® is a health-related fitness test, developed by The Cooper Institute and adopted as the national fitness assessment by the President's Council on Fitness, Sports and Nutrition [19]. Since 2011, Georgia Official Code (20-2-777) requires all classes taught by a certified PE teacher to administer FitnessGram to all students at least once per year. Although PE teachers in the state of Georgia have been trained to administer the FitnessGram assessment, and were provided with standardized scales and height charts, PE instructors and other staff assisting with the assessment were provided with refresher training on the protocol through face-to-face and distance learning materials already developed and widely used by HealthMPowers. Scores were recorded in the FitnessGram software at the student level. Two measures were used from the FitnessGram: cardiorespiratory fitness and body mass index.

Cardiorespiratory fitness is measured by the Progressive Aerobic Cardiovascular Endurance Run (20 m), categorized as the number of laps completed. Student body mass index is based on height and weight measurements taken by trained PE teachers, using the Georgia FitnessGram protocols and software to calculate BMI.

2.8.1.7. Student-level fidelity of intervention measure: physical activity. For all enrolled students, PA was objectively measured at two points each year using 5-day accelerometry. Students wore an ActiGraphwGT3X-BT accelerometer (ActiGraph, Pensacola, FL) for one week (5 consecutive school days), at two time points (fall/spring) during each of the two intervention years. Accelerometers were attached to an elastic belt which students wore on the waist. Students were assigned an accelerometer with a specific number on the belt. Students entered class each day, selected their belt with accelerometer and attached the belt around their waist. Students wore the accelerometer belt for the entire school day. At the end of the school day, students removed the accelerometer belts and placed them back into the plastic case in the matching, numbered slot. During the Spring data collection period, in addition to the school day data collection, a subset of students wore the accelerometers at home to capture information about out-of-school-time PA.

Data were aggregated over 15-s epochs to capture the sporadic nature of children's activity and to mirror the collection intervals from which the Evenson cut points were developed [20]. Accelerometer data were used to objectively measure metabolic equivalents (METs), which are categorized as: time spent in sedentary behavior (<1.5 METs), light PA (1.5–3.99 METs); moderate PA (4–5.99 METs), vigorous PA (≥6 METs), and moderate and vigorous PA (>4 METs). In addition, we measured PA intensity, using mean activity counts per minute divided by each of the three axes, as well as sum of counts, average counts, and maximum counts. Greater counts per minute indicate a higher intensity.

2.8.2. School-level measures

2.8.2.1. School physical activity survey. A modified version of the School Physical Activity Policy Assessment (SPAPA) [21,22] was used to document relevant policies and practices at each school. This survey was administered in two time periods: Fall of 2018–2019 school year and Fall of 2019–2020 school year.

2.8.2.2. Observational audits of school facilities. School visits were conducted in both Spring 2019 and Spring 2020 to obtain data that allowed for the characterization of differences in school facilities relevant to student PA. The Observational School Environment Checklist (OSEC), which assesses the physical and structural environment of schools [23], was used to collect this information. The tool assesses the physical environment in four main locations (cafeteria, lobby/hallway, gym, outdoor areas), with the latter three used in this study (cafeteria is omitted due to this project's focus on PA but not nutrition). The tool was developed with input from school wellness experts and was tested and refined in more than a dozen schools. The observational visit took about 2 h per school, and included taking photographs of school facilities to allow double-coding and calculation of inter-rater reliability.

2.8.3. Fidelity of implementation measures: intervention condition

School calendars served as one measure of fidelity to implementation of the school PA plan. Time scheduled for PE, recess, and other PA activities were extracted from calendars. Teacher PA tracking surveys were collected quarterly, as a self-report measure of classroom PA implementation. Aggregated student accelerometry data (see section 2.8.1.9 above) are used to confirm that changes in school practices are resulting in quantifiable changes to student PA.

2.9. Planned analyses

The primary objective is to determine the association between PA and several academic achievement outcomes (i.e., standardized test scores, teacher-assigned grades), both in the short- and long-term. With cooperation from the district, we will be able to utilize linked data at the student level. We will use hierarchical linear models [24,25] with students at level 1; classrooms at level 2, and schools at level 3. Generally, the following model is specified with modification depending on the objective being addressed (modifications by objective are mentioned after):

Level 1 (student)

$$y_{ijk} = \beta_{0jk} + \beta_{1jk}(PA_{ijk}) + \sum_{s=2}^{S} \beta_{sjk}(Cov.s_{ijk}) + e_{ijk}$$

where y_{ijk} is the outcome for student i who has teacher j in school k, PA_{ijk} is the student's measured PA, and all remaining S covariates are captured in the summation, including student-level control variables, potential mediators, and potential moderators (including interactions), depending on the objective. The term β_{0jk} is the predicted value for a student given zero values for all predictors, β_{1jk} is the coefficient of PA and indicates the expected change in the outcome given a one unit increase in PA, β_{sjk} is the coefficient for the sth predictor (whether that be a control, potential mediator, or moderator).

Level 2 (teacher)

$$\beta_{0jk} = \gamma_{00j} + r_{0jk}$$

$$\beta_{1jk} = \gamma_{10j} + r_{1jk}$$

$$\beta_{sjk} = \gamma_{s0j} + r_{sjk}$$

where each coefficient at level one is an outcome in an equation with a fixed effect (γ) and random error term (r). Although each coefficient is described here with a random effect (r), control variables will have variance terms set to zero whereas mediators and moderators will have variances estimated. Because teacher-level covariates are not of interest in meeting the objectives, none are specified.

Level 3

$$\gamma_{00j} = \delta_{000} + \sum_{m=1}^{M} \delta_{m00}(Cov.m_{00k}) + u_{00k}$$

$$\gamma_{10j} = \delta_{100} + \sum_{m=1}^{M} \delta_{m00}(Cov.m_{00k}) + u_{10k}$$

$$\gamma_{s0j} = \delta_{s00} + u_{s0k}$$

where M is the total number of control variables or potential school-level moderators. The formula for γ_{00j} contains the main effects of each potential school-level moderator and the formula for γ_{10j} allows for cross-level moderation to be evaluated where, seen after substitution, the interaction effects of school-level variables and PA may be evaluated. Across all levels, the residual terms (e, u, and r) are taken to be normally distributed with a mean of zero and a variance that will either be estimated or fixed to zero, depending on the role of the variable and objective.

2.9.1. Physical activity and achievement

Several similar models are planned to evaluate the association between PA and achievement (objective 1). Outcomes for models include (1) 4th grade standardized test scores in mathematics, ELA, and lexile scores, (2) 4th grade teacher-assigned course grades in mathematics, reading, writing and spelling, and (3) 5th grade teacher-assigned course grades in mathematics, reading, writing, and spelling. The intercept and coefficient of PA will be allowed to vary across levels whereas control variable will have variances fixed to zero. Third grade data and other student-level variables for each of the academic outcomes will be utilized as covariates.

2.9.2. Mediator analyses

A secondary aim is to examine whether higher student PA is associated with greater academic achievement, via proximal education outcomes (attendance and tardiness) or by health outcomes (cardiorespiratory fitness, body mass index). Mediating relationships can be evaluated using a series of multilevel models. In the first model, the potential mediator is specified as the outcome and the coefficient of PA recorded (objective 2.1). In the second model, both the potential mediator and PA are included as predictors of the academic achievement variable (objective 2.2). The coefficient of the mediator is recorded. The product of the recorded coefficients is the estimate of the indirect effect, the confidence interval for which can be determined using monte-carlo methods [26]. The statistical significance of the indirect effect is then determined (objective 2.3) using this confidence interval. Given that level two and three predictors are not of interest in the identification of mediating relationships, the above model specification is modified such that no predictors at level two or three are included (see Fig. 1).

For example, one potential mediator of the relationship between PA and teacher-assigned grades in 4th grade is the number of absences a child has in 4th grade. In the first model for testing mediation, 4th grade absences are predicted by 4th grade PA. In the second model, both 4th grade PA and 4th grade absences are specified as predictors of teacher-assigned classroom grade at the end of 4th grade. The coefficient of PA from the first model and the coefficient of number of 4th grade absences from the second model are multiplied together to give an estimate of the indirect effect of PA on 4th grade teacher-assigned grade through the mediator of number of absences. Using the monte-carlo method and online tools provided by Preacher and Selig [27], the confidence interval for this indirect effect may be estimated with supplied values of standard errors and parameter correlation.

2.9.3. Moderator analyses

Additional research aims involve examining moderators of the relationship between PA and outcomes of interest, through the testing of theoretically justifiable cross-level and within-level interaction terms. In the presented models, potential moderators are now included in the level 3 model, such that the main effect of the potential moderator is included in the equation for γ_{00j} and the assessment of the cross-level

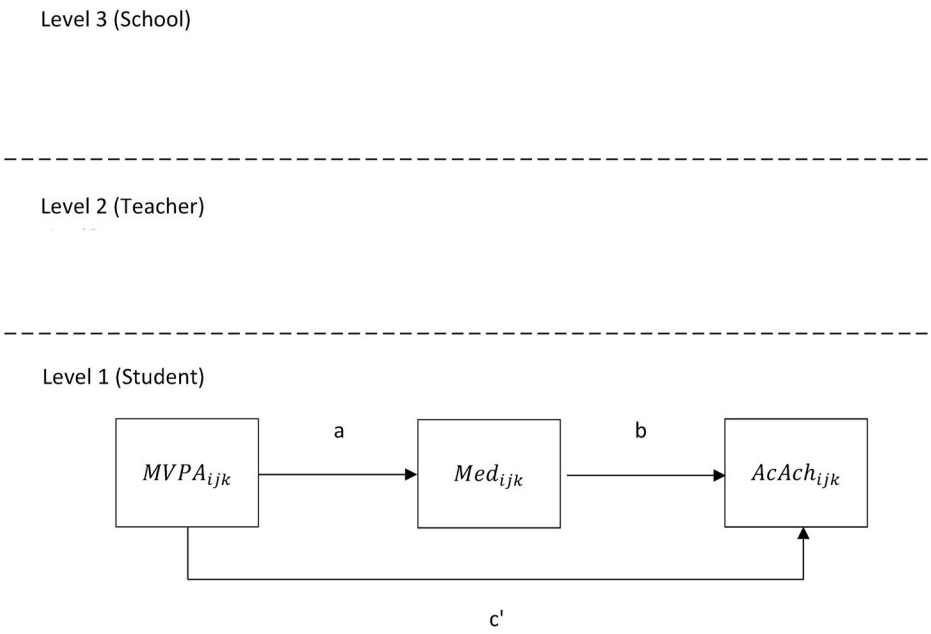

Fig. 1. All variables of interest are at the student level while the clustered nature of the data are still accounted for in the multilevel structure. The product of the *a* and *b* paths is the estimate of the indirect effect and *c*' the direct effect remaining of MVPA on academic achievement after parsing out the mediating effect. MVPA = moderate to vigorous physical activity, Med = mediator, AcAch = academic achievement.

interaction term is made possible by including the same moderator in the equation for γ_{10j}. A key question of interest, for example, is to assess whether the association between PA and achievement is comparable for higher-SES and lower-SES schools. In prior work, we found the effect of student cardiorespiratory fitness on academic achievement was stronger in high-SES schools than in lower-SES schools [28]. Similarly, this study will examine how school characteristics moderate these relationships. Furthermore, school characteristics other than demographics may moderate effects. In Georgia, schools with the highest poverty (80–100% FRPM) had the least opportunity for PA [29] and are less likely to have PA facilities such as a playing court or track [30]. Such disparities in school environments are likely to impact whether PA improves academic outcomes for students.

Student-level characteristics may also moderate the relationship between PA and outcomes. For example, student socioeconomic status and race/ethnicity are associated with education and health outcomes, therefore programs that increase PA may yield larger benefits for low-income and racial/ethnic minority students and thus help to narrow the achievement gap. Socioeconomic status and race/ethnicity have a great impact on education outcomes, with much variation in student performance attributable to demographics [31,32]. This study will examine whether all students benefit similarly from increased PA, through interaction terms in level 1 (with main effect and interaction captured in the summation of the level-1 model). Expected student-level moderators include race/ethnicity, FRPM eligibility, and gender.

2.9.4. Association between changes in PA and changes in grades

The fourth objective is to evaluate the relationship between changes in PA and changes in grades between the first semester of fourth grade and the first semester of fifth grade. The model utilized to evaluate this relationship is similar to the model to investigate Objective 1, except that the difference in PA between 5th grade and 4th grade measurements will be the focal predictor and the outcome will be the difference in teacher-assigned grades in 5th grade and 4th grade.

2.9.5. PA dosage

Objective 5 requires specification of specific cut-points of PA that have been shown to be relevant in the literature and can offer practical guidelines to schools. One such cut-off is 30 min of in-school MVPA per day. This threshold is based on the recommendation that children should engage in 60 min of MVPA per day and nearly half of the waking hours for children during the week is spent in school [4,5]. Another threshold of interest in the present analysis is 45 min of average MVPA. The *Health Empowers You!* program is designed to increase student PA with a goal of 45 min of PA; therefore, evaluating this threshold as a benchmark for MVPA is relevant. Finally, 15 min of average MVPA is another threshold because it offers insight into potential benefits of having children routinely participate in any physical activity in-school and offers a convenient gradation of average MVPA in conjunction with the 30- and 45-min thresholds. These thresholds are evaluated by including indicator variables at level 1 of the models with each defining a different range of time in MVPA. Indicators are specified for the range of average MVPA between 15 and 30 min, between 30 and 45 min, and 45 min or more. Average MVPA of less than 15 min is the reference group.

2.10. Power calculation and sample size

Power was calculated using simulation. Because 161 hypotheses are tested, a Bonferroni correction to the alpha level of 0.05 results in an adjusted alpha of approximately 0.0003. Three levels of sample size are considered for the analysis. There are 40 schools within the school district agreeing to randomization. Given the number of students in the participating schools and our primary interest in student-level relationships, the study is adequately powered to detect even marginal effects. For example, specifying an unconditional ICC of 0.25 (across levels 2 and 3) based on Hedges and Hedberg [33] and a standardized effect size of 0.25 between PA and academic achievement (similar to the smallest observed effects found in meta-analytic reviews of the relationship [35,36]), 40 schools with 6 teachers per school and 20 students per teacher yielded power of 100%. For student-level moderator analyses, power with regard to the detection of moderator effects of substantive interest were evaluated. Based on third grade grades, an effect size of 0.25 is a difference in grades of 2.11 (for writing) to 2.38 (for math). An effect size of 0.5 is a difference in grades of 4.22 (for writing) to 4.76 (for math). These differences are considered substantively important as they capture essentially a quarter to one-half letter grade

difference. Based on effect sizes of 0.25 and 0.5 and the previous conditions, the study will have power of 60% and 100%, respectively. For analyses with school-level moderators, the same effects were evaluated yielding power of 99.9% and 100%, respectively. Investigation of potential mediators of the relationship between MVPA and achievement are uncommon in the literature; therefore, two scenarios were evaluated for power. If the total effect of MVPA on achievement is 0.25 (based on the previously used conservative estimate of the main effect), and 25% of this effect is mediated, then the direct effect of MVPA is 0.1875 and the indirect effect is 0.0625. If 50% of the total effect is mediated, then the direct effect is 0.125 and the indirect effect is 0.125. In both of these two scenarios with the proposed data collection power is 100% to detect the indirect effect. In sum, the study is adequately powered to detect effects of interest.

3. Discussion

This manuscript describes a planned investigation of the relationship between PA and academic outcomes in the context of implementing the *Health Empowers You!* Intervention, designed to increase student PA by changing school practices. An extensive accelerometry data collection protocol will yield information that allows for examination of the intervention's fidelity in terms of student PA levels (i.e., whether PA increases at schools in the intervention condition). This paper describes the rationale, aims, intervention design and theory, recruitment and student enrollment, measures, and analysis plan for this trial. This study is unique in the extensive use of intensive, objective measurement of student PA using accelerometry, which will allow for consideration of student-level mechanisms of change such as how individual characteristics impact changes in academics, and examination of what 'dose' of daily PA is sufficient to elicit improvements in academics.

3.1. Strengths

This study has at least four strengths. First, using objective measurement of PA through accelerometry is important, and is supplemented by a student self-report survey to validate accelerometry. Second, the intervention is based in ecological theory, focusing on changing school environments. It is also pragmatic, being aligned with the Whole School, Whole Child, Whole Community model [15,16], and utilizing the CSPAP framework [10,11] that allows schools flexibility and adaptability in selecting PA strategies that are feasible and acceptable for their specific needs and resources. Third, this study utilizes a broad range of indicators of academic outcomes, including not only a crucial outcome measure—standardized measures of academic achievement on mathematics and English language arts tests that are aligned to the Common Core State Standards—but also other outcomes that are predictive of student success such as absences, tardiness, and teacher-assigned grades. Fourth, this study has a large sample size, with 40 schools, and a racially and economically diverse cohort of students that will be followed for two school years, which is a much longer period than many prior studies.

3.2. Limitations

As with any research study, this trial has limitations. First, there is not an objective accelerometry measure of student PA at baseline (prior to the beginning of the intervention, in grade 3). Because of this, it will not be possible to examine student-level growth curves for PA from before to after the intervention; however, it will be possible to compare changes over the subsequent two years for students in each of the two conditions. Comparison of these changes will allow for inferences about the impact of the intervention on a key indicator of intervention fidelity, testing whether the intervention increased PA opportunities for students and, consequently, increased student PA levels. Second, although the data collection plan includes 24-h accelerometry from a subset of students, this will not yield a detailed contextualization of the types of PA that students engage in outside of school hours. This study will not gather extensive, detailed data regarding student PA behaviors outside of the school environment (e.g., settings such as at home and in the surrounding neighborhood), nor will it gather data during times such as on the weekend or over the summer between school years. Third, given the disruption in data collection by COVID-19, standardized test scores are only available for the 3rd and 4th grade years, requiring reliance on teacher assigned grades for investigations of change between 4th and 5th grade. Doing so, we are unable to investigate the relationship between changes in PA and changes in pure measures of academic content knowledge. Lastly, the study takes place in one school district, in one state in the US. The district and the schools within it have a broad range of variation in student demographics such as socioeconomic status, and student race/ethnicity, with most schools having diverse student bodies (7 schools have >50% students who are Latino, 3 have >50% students who are Black, and 6 schools have >50% students who are White). However, this sample is not necessarily representative of other schools, regions, states, or the nation, which limits external generalizability.

4. Conclusion

Increasing evidence shows that healthy students are better learners [15,34], and that ensuring that elementary school students have sufficient opportunities to be physically active while at school can improve academic outcomes [6,14]. However, several questions remain, such as what dose of PA is required to promote such improvements, and whether this effect is stronger or weaker for some students than for others, or at some schools versus others. This study adds to prior research that examined the impact of school-based PA on student academic outcomes, by being sufficiently powered to statistically explore mechanistic aims such as identifying the potential moderators of PA's association with academic outcomes. The extended nature of the intervention, over two years, combined with the tracking of a longitudinal cohort of students will allow for examination of the sustained impacts on student outcomes, as a result of changing school-based practices to increase the amount of PA that students engage in while at school.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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