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Physical Activity Across the Curriculum (PAAC3): Testing the application of technology delivered classroom physical activity breaks

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Abstract

Only 43% of children in the U.S., ages 6-11 yrs., meet current physical activity (PA) guidelines. To satisfy the MVPA requirement, schools have begun incorporating MVPA in the form of activity breaks or MVPA academic lessons. We completed two, 3 academic-yr. cluster randomized trials (DK61489, DK85317) called "Physical Activity Across the Curriculum" (PAAC) which involved increasing MVPA in the classroom. Across 3-yrs. teachers in PAAC schools delivered ~60 min/wk. (12 min/day) of MVPA. Although short of our MVPA goal (20 min/d), the PAAC approach substantially increased in-school MVPA. Teacher reluctance to devote additional time to develop and integrate PA lessons into their curriculum was the overwhelming barrier to meeting the MVPA goal. Therefore, to reduce barriers to delivery of classroom PA we developed a 3-academic yr. cluster randomized trial (2 yrs. active intervention, 1 yr. follow-up) to compare the effectiveness and sustainability of technology delivered (PAAC-R) and classroom teacher delivered (PAAC-T) activity breaks for increasing classroom MVPA in elementary school students in grades 2 and 3 at baseline who will progress to grades 4-5.

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Keywords

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Introduction

Only 43% of children in the U.S., ages 6-11 yrs., meet current guidelines for participation in moderate-to-vigorous physical activity (MVPA, ≥ 4 METs, 60 min/day.) (1). The percentage of children meeting these guidelines decreases to 7.5%, and 5.1% in 12-15, and 16-19 yr. olds, respectively (2). The adverse impact of low MVPA on both physical health has prompted the development and evaluation of interventions to encourage children to adopt and maintain a more active lifestyle.

According to the Institute of Medicine (IOM), “Children spend up to half their waking hours in school. Schools therefore provide the best opportunity for a population-based approach for increasing physical activity (PA) among the nation’s youth” (3). The IOM has recommended that children accumulate “at least 60 minutes per day of vigorous or moderate-intensity [MVPA] PA more than half [ie, 30 minutes] of which should be accomplished during regular school hours (1)”. However, data suggests in-school MVPA is generally low, with few children meeting the 30 min/d in-school MVPA recommendation (4–7).

Classroom PA breaks have the potential to provide a substantial proportion of in-school MVPA (8), as recommended by the IOM (1), and satisfy MVPA requirements for School Wellness Policies (9). PA breaks provide an interruption in prolonged sitting and have been associated with improved classroom behavior (8, 10), and a positive or neutral effect on academic performance (11, 12). Evidence suggests that the impact of classroom PA on academic performance may be associated with changes in cardiovascular fitness rather than the integration of academic concepts within the physically active lessons (12).

Previously, we completed two, 3-yr. cluster randomized trials (DK61489, DK85317) which increased MVPA in elementary school classrooms using an approach called “Physical Activity Across the Curriculum” (PAAC) (11, 13–15). The primary outcome of PAAC was to assess change in BMI in children between schools randomized to intervention or control (no intervention), and the primary outcome of “Physical activity and academic achievement across the curriculum” (A+PAAC) was to determine the impact of the PAAC intervention in children between schools randomized to intervention or control for academic achievement. In both trials, elementary school classroom teachers were trained to deliver two, 10-min physically active academic lessons each day over 3 yrs. to students in grades 2 and 3 at baseline. The goal of PAAC was for teachers to deliver ~90 minutes/wk of classroom PA (9, 10-minute lessons/wk), while in A+PAAC teachers were instructed to deliver ~100 minutes/wk of classroom PA(20 min/day, 5 days/wk). Teachers in both trials delivered ~60 min/wk. (12 min/day) of MVPA (~ 4.2 METs), assessed by indirect calorimetry, across3 academic yrs. (11, 15–17). Although short of our goal (20 min/d), the 12 min/day of MVPA represents 40% of the IOM recommendation (1), and is equal or greater than the amount of MVPA delivered in 3 physical education (PE) classes/wk (11,13–15). Both trials provided extensive teacher training, resource materials, including lesson plans, and support. Despite these efforts, focus group discussions indicated that the overwhelming barrier to meeting the MVPA goal was teacher reluctance to devote the additional time they perceived was required to integrate physically active academic lessons into their existing academic curriculum.

In total, results from previous trials demonstrated the feasibility of delivering MVPA in a classroom, and the potential for classroom MVPA to provide a significant proportion of the recommended daily MVPA, and increased total daily MVPA, in elementary school children (18– 20). However, integration of MVPA with academic content diminished the magnitude of intervention delivery. Therefore, to improve the amount of MVPA delivered in the classroom we will investigate the effects of MVPA delivered by the classroom teacher or via remote video delivery without integration of academic lessons.

Methods and Materials

Design overview.

Physical Activity Across the Curriculum 3 (PAAC 3) is a cluster-randomized trial with 2 yrs. active intervention (Beginning in Fall 2018) and 1 yr. follow-up designed to compare the effectiveness and sustainability of remotely delivered (PAAC-R) and classroom teacher delivered (PAAC-T) activity breaks for increasing classroom MVPA in elementary school students in grades 2 and 3 at baseline. Teachers in both groups will be trained to deliver the intervention and asked to provide two 10-min activity breaks each day across the 3-yr. intervention. The primary outcome, minutes of MVPA during PA breaks, will be assessed by accelerometer on 2 randomly selected weeks, one in each semester, in each of the 3 study yrs.

Intervention-theoretical model.

Our intervention is grounded in Social Cognitive Theory which emphasizes the interaction of personal, behavioral and environmental factors (21). Activity breaks represent a change in the classroom environment such that all students are exposed to increased MVPA, thus increasing the probability that MVPA will be performed and potentially resulting in increased self-efficacy for PA. Active participation with other students and/or encouragement for participation in activity by the teacher may serve to engage students and reinforce the importance of PA (15).

Recruitment-schools.

Approximately 16 schools will be recruited from both urban and rural settings within a 50-mile radius of either Lawrence or Kansas City, KS. School districts will be contacted by phone and meetings will be scheduled with administrators/teachers of interested districts to explain the project and to solicit participation. All schools will be compensated with $1,000 for participation at the completion of the trial, i.e., end of yr. 3.

Randomization.

Schools will be stratified within districts (urban vs. rural, population > 50,000) and randomized to either PAAC-R or PAAC-T within each stratum. Stratified randomization will minimize imbalance in cluster size (schools) between intervention groups, and should control for potential confounders, e.g., differences in sex, minorities, free and reduced lunch, etc. Randomization will be completed in 2 waves of ~8 schools each (4 PAAC-R, 4 PAAC-T) using the randomization procedure in SAS (PROC PLAN).

Student-Recruitment/Eligibility.

The intervention will be delivered over 3 academic yrs. to all students in participating schools who are in grades 2 and 3 at baseline. However, outcome assessments will be obtained only on eligible students in each school who provide assent and parental consent. We considered various scenarios for inclusion, as there are likely some students who are unable to fully perform the intervention activities or complete the outcome assessment. An elementary/adapted PE specialist, will be available to provide teachers with modifications of activity breaks to accommodate students with disabilities (11, 15). However, not all students will be eligible to complete outcome assessments. For example, a student who is confined to a wheel chair, blind, or intellectually disadvantaged may be unable perform tests for cardiovascular fitness or MVPA using accelerometers. Cluster-randomization of schools should provide equal distribution of students with disabilities across intervention groups. The more inclusive approach will provide a better representation of student characteristics and thus improve the generalizability of our results.

Student Consent.

Student recruitment will be initiated by contacting parents via flyers that explain the study and describe student capabilities required to complete the outcome assessments. Parents with interested students will be invited to attend an information meeting to be held at the school during the week in the early evening. Multiple sessions will be scheduled to accommodate as many parents as possible and the meetings will be conducted by research staff. Teachers will be invited to attend these meetings but will not be involved with the consent process and will not collect individual level participant data during the study. From our experience with school-based interventions, including teachers who are familiar with the parents provides an elevated level of comfort regarding allowing their children to participate in research. The PA breaks and all assessment procedures will be thoroughly explained. Students will be enrolled in the trial only after providing signed parental consent and signed student assent. This recruitment strategy was successfully implemented in our previously completed classroom-based PA trials (11, 15).

Teacher-Recruitment/Consent.

All teachers (e.g., classroom, special educators, music,) in participating schools will have the option to enroll in the PAAC Teacher Study (See Exploratory Outcomes). Teachers interested in participating will be invited to attend an information meeting at the school after the normal school day where all assessment procedures will be thoroughly explained. Teachers will be enrolled only after providing signed consent. Teachers are not required to enroll in the PAAC Teacher Study.

Intervention Overview

Activity breaks-general description.

Activity breaks will be designed for delivery in the classroom without reconfiguration of the classroom space. Activities will emphasize whole body movements, using large muscle groups, e.g., the lower extremity, and will elicit energy expenditures of ≥ 4 METs. Each break will include multiple activities, with a different activity ~ every 20-30 secs. Teachers will be asked to facilitate (PAAC-R) or deliver (PAAC-T) 20 min. of MVPA in activity breaks each school day. We will suggest delivery of 2-10 min breaks/day, one in the morning and one in the afternoon. However, teachers will be instructed to modify this schedule according to their specific needs. To allow this flexibility in the PAAC-R group, we will develop pre-recorded breaks of both 5- and 10-min durations (+1 minute) that can be delivered individually, or combined, to meet the 20 min/day goal.

PAAC-R-development.

We will develop ~175 video recorded activity breaks for use in the current trial with input from an advisory panel. This number of breaks will provide a variety of options for teachers across the ~180 days of the academic yr. and will allow us to replace activity breaks that are used infrequently with potentially more useful options. Activity breaks for this study will be professionally recorded and will include appropriate backgrounds and music (See Video1).

Intervention delivery.

Teachers in both intervention groups will be provided access our study website to utilize research materials and communicate with study staff. Teachers in PAAC-R and PAAC-T schools will be provided access only to sections of our trial website specific to their intervention group.

PAAC-R.—Teachers in schools randomized to PAAC-R will be asked to log on to the PAAC-R section of our trial website and select an activity break that will be displayed on a video monitor in the classroom. Videos may be played in any order. Time and frequency of access to activity breaks will be tracked (Wistia.com) on the website to document intervention delivery. The PAAC-R section of the website will contain examples of strategies for facilitating student participation in activity breaks, as well as a synopsis of key points covered in the PAAC-R training sessions. Facilitating is defined as verbally encouraging student participation in the video activities and assisting students with modifying activities, if necessary. The teacher may also choose to participate if he/she would like to model behavior.

PAAC-T.—Teachers in schools randomized to PAAC-T will also be asked to log on to the PAAC-T section of our trial website that will contain timers (i.e., 5 and 10 minute) for teachers to indicate the start and stop of each activity break using a provided activity timer (5 or 10 minute). Similar to the PAAC-R group, time and frequency of access to the timers will be tracked on the website to document intervention delivery. The PAAC-T section of the website will contain an electronic version of the teacher guide (flip chart describing activities for inclusion in activity breaks) that will be provided to all teachers in PAAC-T schools, as well as a synopsis of key points covered in the PAAC-T training sessions.

Reminders.—To facilitate delivery of activity breaks, teachers will be instructed to set a reminder chime (i.e., late morning and late afternoon) on their computers. During the 2-yr. active intervention, teachers will be encouraged to contact trial staff with any questions or issues that should arise. During the 1-yr. follow-up we will not contact teachers or send reminders for activity breaks. However, we will respond to teacher requests sent to us and will visit classrooms to perform outcome assessments.

Teacher training.

Teachers in both intervention groups will be trained to deliver their respective interventions in separate, regularly scheduled school in-services sessions, an approach that was well accepted and employed successfully in our previous school-based trials (11, 15) .

Training delivery.—Training will be delivered face-to-face prior to the start of school in the fall of each year. During training, teachers will have the opportunity to share ideas regarding strategies for delivery/facilitation of activity breaks with other teachers and study staff . This aspect of the training is in accordance with the guidelines for active teaching (22) for small group interaction (23), cooperative learning (24), and ideas for reciprocal teaching (25) which should ensure that the teachers leave training sessions with enhanced self-efficacy to deliver/facilitate activity breaks, a feeling of ownership in the project, and a sense of professional growth. Attendance at training sessions will be recorded and used in our process evaluation. Teachers will receive $50 on completion of each training session.

Training session frequency.—We will conduct a ~2-hr. initial training session at the beginning of intervention yr. 1 (Fall), with 1-hr. refresher sessions conducted at the beginning of the Spring semester (January) in yr. 1 and in the beginning of the Fall and Spring semesters in yr. 2. The proposed training time is reduced compared with our previous classroom PA trials based on teacher feedback and the elimination of the integration of PA and academics in this trial.

Training session content.—Information regarding the prevalence of low PA, the importance of PA, and current policy recommendations for PA, both in and out of school, for elementary school children will be included in training of both groups. Teachers in both groups will also be familiarized with procedures required to access their respective sections of the trial web site, and classroom management techniques for delivering activity breaks, safety procedures and information on observation of student behavior during PA, e.g., enjoyment, displeasure, excessive fatigue, etc. The definition of MVPA and the importance of delivering MVPA (> 4 METs) in the classroom, and strategies for planning and delivering activity breaks to include smooth transitions between activities will be emphasized in the PAAC-T training. PAAC-T training will also emphasize the importance of teacher modeling during activity breaks while PAAC-R training will emphasize strategies for encouraging student participation in activity breaks.

New teachers.—Using the protocol as previously described, study staff will individually train teachers hired at participating schools after initiation of the intervention.

ASSESSMENTS

Schedule.

Our primary outcome is the average min/day of MVPA during activity breaks and will be assessed by accelerometer during one randomly selected 7-day period each semester (Fall: September thru early December; Spring: February thru early May) in each of the 3 study yrs. Secondary aims based on accelerometer data, i.e., in-school and total daily MVPA will be assessed on the same schedule as the primary outcome. Height and weight for the calculation of BMI (kg/m^2), waist circumference, and cardiovascular fitness will be assessed in the Fall of trial yr. 1, and in the Spring of the academic yrs. 1,2, and 3. Energy expenditure of activity breaks will be assessed in a volunteer sample of 50 students, 25 per intervention group across the 2 yr. active intervention (See Table 1).

Location.

Except for out of school MVPA, all assessments will be obtained at the school during the school day. Anthropometric assessments will be obtained in a private room, and cardiovascular fitness will be assessed in a gym or all-purpose room at the respective schools.

Personnel/blinding.

Research assistants will complete a 1-hr. training session prior to collecting data at each collection period. All research assistants must achieve inter-rater reliability ≥ 0.90 prior to being eligible to collect data on height, weight, waist circumference and cardiovascular fitness. Research assistants who fail to meet this standard will be retrained, and retested. Research assistants failing to achieve the 0.90 standard on the second test will be dismissed. Research assistants, data entry personnel, and data analysists will be blind to intervention group.

Primary/secondary outcomes

Physical activity.

Our primary outcome will be the average number of minutes of MVPA during the period of activity breaks. Start and stop time for activity breaks will be determined from computer records of activity break delivery as previously described. As secondary aims, we will also assess sedentary time and minutes of MVPA during both the complete school day, defined by each school schedule, and across the 7-day monitoring period for both children and teachers..

Equipment.—PA in students and classroom teachers will be assessed using an ActiGraph model wGT3x-BT (3.3 x 4.6 x 3.5 cm, wt. = 19 g., dynamic range ± 8 g) portable tri-axial accelerometer (ActiGraph Corp, Pensacola, FL). The ActiGraph provides valid and reliable assessments of PA in children (26–28) and adults (29–31). ActiGraphs have been widely used to describe PA levels in children (32) and to evaluate change in PA in elementary school children in response school based interventions (33–36).

Protocol.—There is a lack of consensus on the best protocols to collect, process, and score ActiGraph data (37–40). Thus, our decisions regarding ActiGraph location, monitoring period, data processing etc. were selected based on current practice as described as follows: participants will be asked to wear the ActiGraph on a belt over the non-dominant hip at the anterior axillary line 24 hrs./d for 7 consecutive days, except for bathing, swimming, and contact sports, a randomly selected time each semester (Fall: September thru early December; Spring: February thru early May) in each of the 3 study yrs. A 7-day monitoring period provides a reliable estimate of MVPA (38, 41, 42) in response to school-based interventions (33, 36, 43– 45). We will request wear time of 24-hrs. rather than only during the "waking" day based on results of Tudor-Locke et al (46) that demonstrated ~62 min/d of additional wear time in children (~ 10 yrs. old) using a 24-hr., compared with a "waking" day protocol. The hip rather than the wrist location will be used due to the lack of comparable data and established protocols for assessment of MVPA using wrist-worn ActiGraphs (47–49).

ActiGraph distribution.—Research staff will visit the classroom in the morning to describe the ActiGraph protocol and to ensure all monitors are properly attached and will return the following week in the afternoon (i.e., Monday morning to Tuesday afternoon, Thursday morning to Friday afternoon etc.), at the end of the school day, to retrieve the monitors. Distributing the actigraph a day prior to activation has been shown to decrease the Hawthorne effect (50). ActiGraphs will be programed to begin data collection at 5 AM the following day and stop at 6 PM at the end of the 7-day period. Data from the first monitored day (i.e. Monday) will not be included in the analysis to minimize any potential reactivity (51). We realize that this protocol will not capture a complete 7-day period; however, data for our primary aim, MVPA during classroom activity breaks, and secondary aim (school day MVPA/sedentary time) will be assessed over 5 complete school days. Children in classes in both intervention groups will be monitored concurrently. Daily reminders (school days) to request compliance with the monitor protocol will be sent to teachers via email.

Data collection.—ActiGraphs will be initialized and downloaded using ActiLife Software version 6.13.3 or higher (ActiGraph Corp, Pensacola, FL) and set to collect in the raw data mode from all 3 axes at 60 Hz. Although the wGT3x-BT collects raw data from 3 axes, results from studies assessing the benefit of 3 axes vs 1 axis (vertical) are conflicting (52–54). In addition, there are currently no established algorithms for using either the raw data or the vector magnitude (square root of the sum of the squares of each of the 3 axes) to estimate MVPA (55, 56). Thus, we will use acceleration data from the vertical axis in this study. This will allow us to obtain data consistent with the preponderance of the literature on MVPA assessed by accelerometer in school-based interventions (36, 43, 57), and to use recommended cut-points for determination of activity intensity for children (58, 59) and adults (60). However, raw data from all 3 axes will be downloaded and stored. This data will be available should algorithms for processing this data become available.

Data processing-students.—Data from students will be aggregated over 15-sec epochs to capture the sporadic nature of children's activity (61) and to mirror the collection interval on which the Evenson et al. cut-points for determining activity intensity in children were developed (59). The use of epoch lengths different from those on which cut-points were established has been shown to introduce significant error in estimates of activity intensity (62). We realize there is continued controversy regarding the "best" cut points for classification of PA intensity (37, 38, 63). We chose the cut-points for children proposed by Evenson et al. (59) which have been shown to provide acceptable levels of classification across sedentary (≤ 1.5 METs; 0-25 counts/15-sec), light (1.5-3.99 METs; 26-573 counts/15-sec), moderate (4.0-5.99 METs; 574-1002 counts/15-sec) and vigorous (≥ 6 METs ; ≥ 1003 counts/15-sec) levels of intensity (58), and have been widely used in school-based interventions (34, 38, 64, 65). Non-wear time for children will be defined as 20 consecutive epochs of zero counts (38, 65, 66). Spurious data for children will be defined as counts ≥ 1,929/15-sec.(40).

Data processing-teachers.—Accelerometer data from teachers will be processed using the protocol used for adults in the 2003-2004 and 2005-2006 cycles of NHANES (60, 67). Data will be aggregated over 60-sec epochs. The following intensity cut-points will be used for teachers: sedentary (< 1.0 METs; ≤ 100 counts/min), light (1.1-2.99 METs; 101-2019 counts/min.), moderate (3.0-5.99 METs; 2020-5988 counts/min) and vigorous ≥ 6 METs; ≥ 5999 counts/min) (60, 67). Non-wear time for teachers will be defined as at least 60 consecutive minutes of zero counts, with allowance for 1-2 min. of counts between 0 and 100. Counts ≥ 20,000/min will be considered spurious and will be deleted (68).

Missing accelerometer data.—Non-compliance with the accelerometer protocol in studies of children ranges from ~ 21-35% depending on the specific study requirements (32, 46, 69). Recent advances in both statistical methods, and in computing power have made it possible to impute missing data with large data sets such as will be collected in the proposed trial, i.e., 2 wk.-long assessments in all students each yr. over 3 yrs. A detailed description of the methods and procedures for handling missing ActiGraph data (non-wear and device malfunction time) is included in the analysis plan section.

Body mass index.

Height and weight for the calculation of BMI (weight kg/height m^2), and waist circumference will be obtained in a private room during the first period of the school day with students wearing school clothes without shoes. Standing height will be measured in duplicate with a portable stadiometer (Model #IP0955, Invicta Plastics Limited, Leicester, UK). Weight will be measured with a portable calibrated digital scale accurate to ± 0.1 kg (Model #PS6600, Befour, Saukville, WI.). Waist circumference will be assessed using the procedures described by Lohman et al (70). Three measurements will be obtained with the outcome recorded as the average of the closest 2 measures.

Cardiovascular fitness.

Cardiovascular fitness will be assessed using the Progressive Aerobic Cardiovascular Endurance Run (PACER). The PACER is based on the 20-m shuttle run (71), and has acceptable validity and reliability across several age groups including elementary school children (72). Students will be instructed to run back and forth between two lines 20 m apart. The pace is initially slow and progressively increases. Students will be paced by a sound (beep) recorded on a CD (FITNESSGRAM®) to indicate when they should reach each end of the 20-m course. Research assistants will observe the test to ensure that students traversed the 20-m distance. The test will be terminated when students fail to traverse the 20-m distance in the time allotted on two (not necessarily consecutive) occasions. Cardiovascular fitness will be defined as the total number of laps completed on the PACER, with a higher number of laps indicating a higher level of aerobic capacity.

Energy expenditure of activity breaks.

Energy expenditure of activity breaks during the school day will be assessed in a volunteer sample of 50 students, 25 per intervention group, stratified by grade and sex, across the 2 yr. active intervention, using a previously validated portable, open-circuit indirect calorimeter (PNOE, Palo Alto, CA ,https://www.mypnoe.com/) which measures breath-by-breath ventilation, expired oxygen, and carbon dioxide (73). Following a 30-min warm up, the calorimeter will be calibrated with known gases. The flow turbine will be calibrated using room air and a standardized gas. The lightweight (~.5 kg) portable system will be attached by a harness around the waist and shoulders of the child before each assessment. During activity breaks, participants will breathe into a facemask that directs air into the unit housing the O_2 and CO_2 analyzers. Data will be retrieved for analysis via Bluetooth and software provided with the calorimeter and aggregated over 20-second epochs for the calculation of 1-min averages. MET levels will be age corrected using the Schofield equation (74) as recommended by McMurray et al (75). These procedures for assessment of energy expenditure were used successfully in our previous classroom-based PA trials (16, 17).

Cost and Cost Preference.

Potential advantages of PAAC-R may include lower costs for delivery and reduced barriers to meeting the activity break MVPA goal. However, we also expect that PAAC-R will have higher training materials and development costs compared to PAAC-T. Average development costs depend on the costs of materials themselves, the number of teachers trained, and the depreciation schedule used. Unfortunately, there is considerable uncertainty regarding appropriate depreciation schedules (76). We will use sensitivity analysis to examine the conditions under which PAAC-R has lower costs than PAAC-T. We hypothesize that PAAC-R will reduce barriers to meeting the MVPA goal. We will use Z-tests to compare the proportions of teachers who prefer remote delivery. We will augment this using contingent valuation, in which teachers express preferences for programs using a brief survey, to examine the perceived worth of the PAAC-R or PAAC-T. Surveys will be administered at the end of the active intervention (2 yrs.) and 1-yr. follow-up (3 yrs.) (77). If the preference questions have acceptable psychometric properties, conditional logistic regression will be used to analyze the effects of differences in teacher attributes, school attributes, anticipated costs, and anticipated gains on preferences for delivery formats.

Exploratory outcomes.

Teacher and student demographic characteristics will be obtained by survey at baseline. Teacher self-efficacy for exercise will be assessed using the Exercise Self-Efficacy Scale of McAuley et al (78). Student self-efficacy for PA will be assessed using the Physical Activity Self-Efficacy Scale (PASES) (79) as modified by Bartholomew et al. (80). Student enjoyment of PA will be assessed using the short form of the Physical Activity Enjoyment Scale (PAES) (81) which has been validated in children (82). All psychosocial measures will be obtained at baseline and Spring assessments across the 3 trial yrs. Descriptive data on schools, e.g., school size, demographics, class size, days in session etc., will be obtained from school records at baseline.

Process evaluation.

Teachers.

We will document teacher exposure to the intervention using attendance records from all training workshops. Feedback on the quality and usefulness of the workshops, to identify training needs, and to potentially modify the training program, will be collected by teacher verbal feedback following each training session. Feedback will be used to inform and improve future training sessions.

Implementation and energy expenditure.

Implementation of activity breaks will be tracked in both intervention groups by log-ins to the trial website, as described previously. Energy expenditure of activity breaks in both groups will be assessed by indirect calorimeter as previously described.

School environment.

School records will be used to track characteristics of the school environment, in addition to basic descriptive data, that may affect activity break MVPA, e.g., teachers trained in the intervention leaving the school, student teacher ratio, special activities reducing class time etc.

External/competinq factors.

Principals of schools in both intervention groups will complete a 3-item survey at the end of each trial yr. to determine if external or competing factors may have influenced intervention objectives, i.e., pose a threat to internal validity.

Sample size/power.—Statistical power to detect a significant effect on activity break MVPA (primary aim) in the proposed cluster RCT design depends on the following parameters: the number of schools (K=16, the number of students per school (J=~100; ~25 students x 2 grades x 2 classrooms), the number of measurements (n=6; 1 wks. x 2 semesters x 3 yrs.), effect size (δ), student-level and school-level intra-class correlations (ICCs; ρ), and the proportion of explained variance in school means by school-level covariates (R^2) (83). We anticipate that on average ~100 students in grades 2 and 3 will participate at each of 12 schools, and that 60% of variance can be accounted for by student and school characteristics shared across participating schools. The ICCs observed in our previous PAAC trial were 0.07 and 0.12 at the student and school levels, respectively. Using this information and Optimal Design 3.01 (84), we estimated minimum detectable effect size (MDES) (85). This approach provides insight regarding the smallest true effect detectable with the proposed sample size with 80% power and Type I error controlled under 5%. The estimated MDES was relatively small, indicating that this trial will achieve satisfactory power if the intervention effect is at least $\delta = 0.35$. In sum, the results of our power analysis suggest that this trial will be adequately powered with a total of 16 schools and ~1,200 students. Missing data will be fully recovered via multiple imputation as discussed subsequently, which will remove or minimize (if present) confounding effects of missingness on our statistical power.

Analysis plans

Baseline equivalence.

To assess the degree to which randomization resulted in equivalent groups, the intervention groups will be compared for student and school demographics, e.g., sex, BMI, school size, class size, % minority, %free/reduced lunch, etc. Baseline equivalence of student characteristics will be examined in two-level hierarchical linear models (level 1 = student; level 2 = school) with a group indicator (PAAC-R vs PAAC-T). Baseline equivalence of school characteristics will be estimated similarly, but in single-level general/generalized linear models, i.e., ordinary or logistic regression. Baseline characteristics that demonstrate group nonequivalence will be controlled in the analytic models as described subsequently.

Data analysis.

Because of the naturally clustered structure of the data, multilevel modeling techniques will be utilized to account for clustering of repeated measurements (level 1) on students (level 2) within schools (level 3). In the primary analysis, a three-level hierarchical linear model will be estimated separately for each primary and secondary outcome, to examine linear/nonlinear change over time, i.e. time effect, overall group difference across time, i.e., group effect, and group difference in change i.e., time-by-group interaction. For example, a significant interaction will indicate that students in the PAAC-R schools achieve more minutes of MVPA during activity breaks compared to students in the PAAC-T schools, and this difference becomes greater over time. Student and school characteristics considered nonequivalent at baseline, or deemed to correlate with the outcomes, will be incorporated into the models as covariates to improve the accuracy of model estimates. A proper error covariance structure will be determined for each outcome by assessing relative model fit, e.g., Akaike information criteria, adjusted Bayesian information criteria. In a secondary analysis, multilevel latent growth curve modeling, a special case of structural equation modeling, will identify the linear/nonlinear pattern of change in each outcome and compare the change pattern between the intervention groups.

Missing data treatment.

Missing due to either attrition, e.g., participant dropout, student/teacher turn over or nonresponse, e.g., ActiGraph non-wear or malfunction, will be handled by multiple imputation, in which expectation-maximization (EM) algorithms supply prior estimates of missing values for a subsequent Monte Carlo Markov Chain (MCMC) procedure (86). Enough imputed datasets will be created to ensure accurate recovery of missing data; and analysis results from each imputed dataset will be combined to make valid statistical inferences. All measured student and school characteristics and design factors (e.g., grade, classrooms, randomization block, group) will be incorporated into the imputation process as auxiliary variables, thereby satisfying the missing at random (MAR) assumption (87).

Discussion

Most children are not meeting PA guidelines and percentage of children achieving those guidelines decreases with age (2). As children spend up to half their waking hours in school, schools provide the environment and opportunity for increasing PA (3). The Centers for Disease Control and Prevention (CDC), in collaboration with the Society for Health and Physical Educators, recommend a Comprehensive School Physical Activity Program (CSPAP). CSPAPs target a variety of PA outlets to increase MVPA in children including: PE; PA before, during and after school; staff; family; and community. Despite being endorsed by the CDC/Society for Health and Physical Educators, and the IOM (1), evidence regarding the effectiveness of CSPAP approaches for increasing MVPA in children is limited and conflicting (34, 35, 43, 88–90). The lack of effectiveness of CSPAPs may be due to the cost and difficulty in implementing this complex intervention strategy. In addition, there is also a trend towards decreasing time for PE, which is a cornerstone of the CSPAP approach. Both of these strategies existing in light of increased pressure to meet academic standards of the Every Student Succeeds Act and Common Core State Standards Initiatives (91). Although 90% of schools follow national, state, or district standards for PE, very few elementary schools require daily PE or provide the amount of PE recommended by the CDC (92) and IOM (1). Data from the 2014 School Health Policies and Practice Study indicates that only 15.3% and 3.6% of elementary schools require at least 3 days/wk., or daily PE, respectively (93). Elementary school PE classes are ~40 min in duration; however, only ~ 33% of class time (~13 min) is spent in MVPA (94–96).

Based on the difficulty implementing CSPAPs and the need to increase the amount of PA achieved in school each day, we developed the PAAC 3 program (11, 13–15). In the previous trials, teachers delivered ~60 min/wk. (12 min/day) of MVPA or ~ 4.2 METs, assessed by indirect calorimetry, across 3 academic yrs. (11, 15–17). Although short of our goal (20 min/d), the 12 min/day of MVPA represents 40% of the IOM recommendation (1), and is equal or greater than the amount of MVPA delivered in 3 PE classes/wk. The previous trials demonstrated the feasibility of delivering MVPA in a classroom, and the potential for classroom MVPA to provide a significant proportion of the recommended daily MVPA, and increased total daily MVPA, in elementary school children. However, innovative strategies to improve the implementation, effectiveness and sustainability of classroom activity breaks, as we have proposed, need to be evaluated.

When developing this program, we considered several alternatives and design features. These options included: delivery of PA during PE; activity breaks vs. active academic lessons; or utilizing existing commercial programs or developing new activity breaks. In contrast to PE or recess, classrooms provide an opportunity for all students to participate in

MVPA that is not skill dependent and without having to make a conscious choice to do so. We chose to investigate activity breaks rather than the integration of activity with academic concepts for 2 reasons. 1) In our previous classroom PA trials 92% of teachers reported that the integration of PA and academic concepts was a major barrier to the delivery of classroom PA (11, 15). Teacher reported burden associated with integrating PA and academics was negatively associated with reported minutes of PA delivered in the classroom ($r = -0.47$, $p = 0.02$). 2) Evidence suggests that the impact of classroom PA on academic performance may be associated with changes in cardiovascular fitness rather than activity integrated with academic concepts (12). Thus, removing the barrier of planning/delivering active academic lessons may increase the potential for delivery of higher volume and higher intensity classroom PA, which has the potential to improve both academic performance (12) and physical health (87, 88). We are aware that pre-recorded activity breaks, accessible by the internet, such as BrainBreaks®, GoNoodle, etc. are commercially available. However, the empirical evidence regarding the intensity, effectiveness, and sustainability of these programs is unknown. Activity intensity is a critical parameter in the association between exercise, cognitive function (92, 93), and health (94). Thus, our activity breaks will be designed specifically to deliver activity of ≥ 4 METs that will be verified by indirect calorimetry during development. In addition, as described above, we will use indirect calorimetry to assess the intensity of activity during activity breaks, as delivered in the classroom, to quantify the actual intensity of activity performed by the students.

Conclusion

In conclusion, PAAC 3 is a cluster-randomized trial designed to compare the effectiveness and sustainability of PAAC-R and PAAC-T for increasing classroom MVPA in elementary school students in grades 2 and 3. Results from PAAC 3 will allow for the evaluation of innovative strategies to improve the implementation, effectiveness and sustainability of classroom activity breaks.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

MVPA	Moderate-to-vigorous physical activity
IOM	Institute of Medicine
PA	Physical activity
PAAC	Physical Activity Across the Curriculum
PE	Physical education

PAAC-R	Remotely delivered physical activity break
PAAC-T	Teacher delivered physical activity break
CDC	Centers for Disease Control and Prevention
CSPAP	Comprehensive School Physical Activity Program

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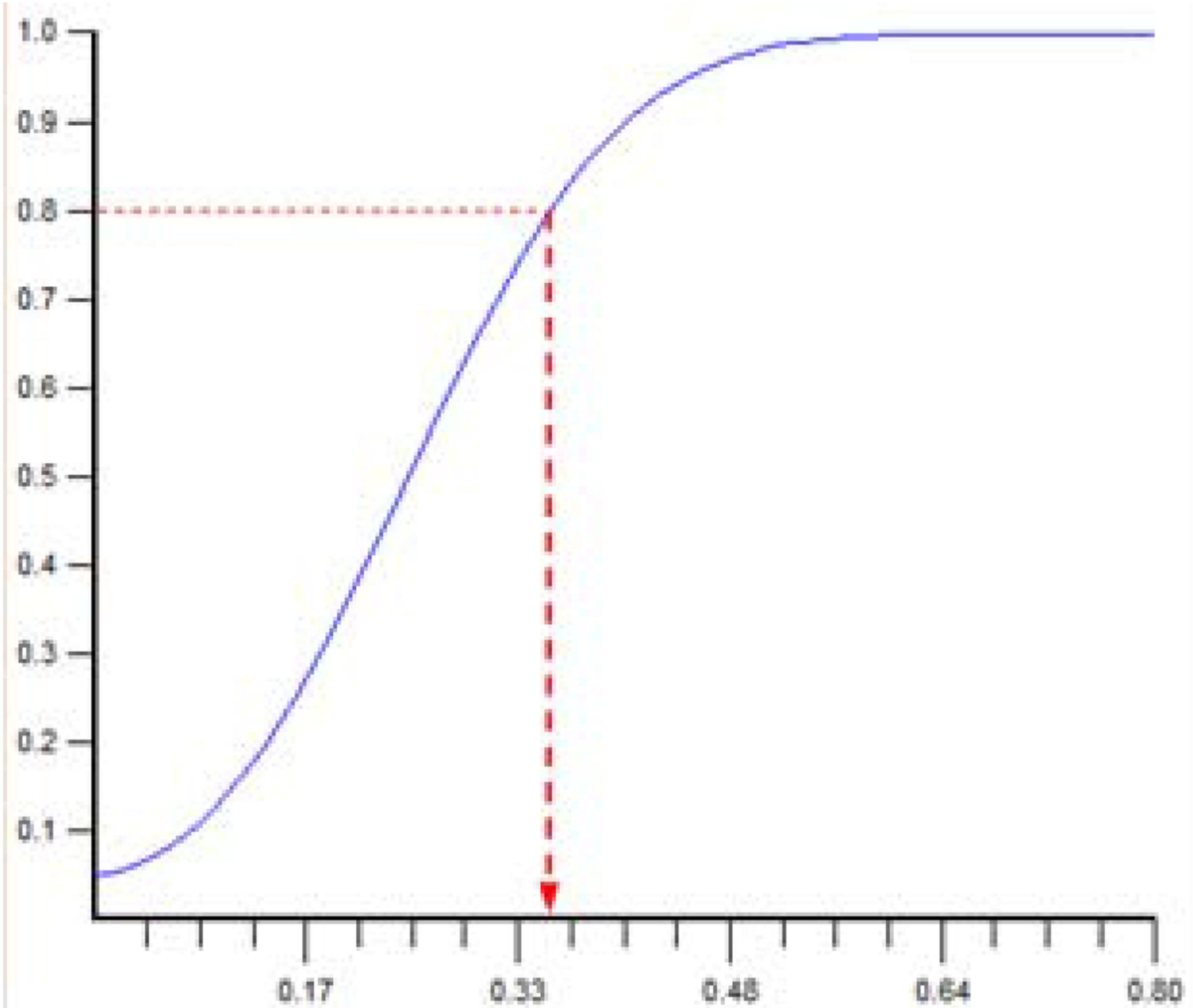

Figure 1.
Power

Note. This figure presents power estmiates (*y–axis*) over a range of effect sizes (x–axis), with n=8, J=100, K=16, $\rho = 0.07$ and 0.12, and R^2=0.60. The red arrow indicates the effect size (δ=0.35) produces 80% power at 5% alpha level.

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Table 1.

Study assessment timeline

	Assessment Frequency	**Year 1 Fall**	**Year 1 Spring**	**Year 2 Fall**	**Year 2 Spring**	**Year 3 Fall**	**Year 3 Spring**
Demographics	Baseline	X					
Questionnaires	Annual	X	X		X		X
Height/Weight/BMI	Annual	X	X		X		X
Cardiovascular Fitness/ PACER	Annual	X	X		X		X
Accelerometer/MVPA	Semester	X	X	X	X	X	X
Energy Expenditure	Continuous	X	X	X	X		
Process evaluation	Continuous	X	X	X	X		
Implementation of Activity Breaks	Continuous	X	X	X	X	X	X
School Environment and Competing Factors	Annual		X		X		X