

Developing and testing an implementation strategy for active learning to promote physical activity in children

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Protocol Title:	Developing and testing an implementation strategy for active learning to promote physical activity in children
Principal Investigator:	Timothy J. Walker, PhD
Population:	Phase 2: 85 Teachers/school staff and about 1100 elementary aged students
Number of Sites:	Single site
Study Duration:	4 years
Subject Duration:	1-2 years

General Information

This study will develop and examine the feasibility of using an implementation strategy for active learning, an evidence-based approach to promote children's physical activity in schools. Developing and testing an implementation strategy for active learning is critical to support the scale-up of these approaches and maximize the public health impact. Dr. Walker is the Principal Investigator and he will receive guidance throughout the study from a mentoring team consisting of Drs. Maria Fernandez, Harold Kohl, Charles Green, and John Bartholomew.

Background Information

Recent research indicates only about 49% of boys and 36% of girls (aged 6-11 years) are meeting physical activity guideline recommendations.¹ As low levels of physical activity in childhood track into adulthood, this puts a generation of children at an increased risk of cardiovascular disease. The American Heart Association recommends population-based physical activity approaches that start in early childhood for cardiovascular disease prevention.² Despite existing evidence-based approaches that increase children's physical activity, implementation remains a challenge, especially in schools.

Schools are a critical setting for physical activity promotion given that they can reach close to 60 million students across the United States.³ Furthermore, children spend the majority of their day in schools where they are becoming increasingly sedentary.⁴ This is because the educational landscape has shifted towards devoting more time to reading and math and less time to physical education and recess. One novel way educators are introducing additional physical activity back into the school day is by incorporating physical movement into academic lessons, an approach known as active learning. There are different forms of active learning that teachers can use. One is developing academic lessons that include physical movements as part of the lesson. For example, a teacher may have students do jumping jacks as part of a counting lesson. Teachers and school staff can also transform a space (e.g., an empty classroom) at each school to facilitate active learning lessons. These spaces (also known as motor labs) have ready-to-use equipment (usually set up in learning stations) that can be portable or remain set up to support teachers when delivering active lessons. For example, students may jump through a rope ladder while reading words in one station or jump on a trampoline 10 times while counting by 10s. Another form of active learning is incorporating physically active breaks during classroom time. These

breaks are not part of the lesson plan but can serve to supplement learning or provide a break from academic content. For example, after teacher delivers lesson content, they may take a break from the lesson material and do a themed dance, and then transition back to the next part of the lesson. There are many existing resources that teachers can use to facilitate these breaks such as GoNoodle, which is an online platform that has a library of videos to support physically active breaks.

Research indicates active learning is a promising and effective way to improve children's physical activity levels.^{5,6} However, these approaches are rarely disseminated and implemented to maximize the public health benefits.^{7,8} Therefore, there is an urgent need for the development of effective implementation strategies to improve the dissemination and implementation of active learning. Until this need is met, the delivery and scale-up of active learning will remain difficult, negatively impacting children's physical activity levels, cardiovascular health, and well-being.

The long-term goal of this work is to improve the implementation and scale-up of evidence-based physical activity approaches to prevent cardiovascular disease. The goals of this research are to: 1) develop a multifaceted implementation strategy for active learning, and 2) conduct a feasibility study to determine whether the developed implementation strategy warrants further testing. The rationale for this project is informed by current work with a local school district in Houston, Texas. The formative research indicates elementary schools are not providing adequate amounts of physical activity to students. Many teachers and staff believe active learning is an effective way to increase students' physical activity levels when used appropriately; however, these approaches are often poorly implemented. Staff reported common implementation barriers consistent with existing research such as time, available resources, school culture, and competing demands.⁹⁻¹¹ Thus, targeting barriers through a systematically developed implementation strategy is likely to improve delivery and effectiveness.

Objectives

The aims of this study are to:

1) Develop an implementation strategy to improve the use and sustainment of active learning in elementary schools. We will use Intervention Mapping, a multi-step approach that includes stakeholder input, behavioral theories, and existing literature to develop a scientifically-based, multifaceted implementation strategy.¹²

2) Conduct a feasibility study to evaluate the impact of the developed implementation strategy on the implementation and effectiveness of active learning. We will assess the acceptability of the implementation strategy and examine its impact on implementation (fidelity) by comparing results between an intervention school (school that receives the implementation strategy) and a comparison school. We will also examine the effectiveness of a specific active learning approach (Action-Based Learning) by comparing students' physical activity levels over time and between an intervention and a comparison school.

Study Design

There are two phases to this study: 1) develop an implementation strategy and 2) conduct a feasibility study to examine the acceptability and impact of the implementation strategy, and effectiveness of active learning.

For the phase 1 (aim 1), we will use Intervention Mapping (IM) to develop an implementation strategy for active learning. IM has been primarily used for developing effective behavioral interventions¹³⁻¹⁷ Recently, implementation researchers have discovered IM to be useful for implementation^{18,19} although IM has been used for this purpose since its inception.²⁰ Intervention mapping is a process that involves five steps for developing and selecting implementation strategies: 1) conduct a needs and assets assessment and identify adopters and implementers; 2) identify adoption and implementation outcomes, performance objectives, and determinants, create matrices of change; 3) choose theoretical methods and select or create implementation strategies; 4) produce implementation protocols and materials; 5) evaluate implementation outcomes. The process is iterative to ensure all adopters and implementers, outcomes, determinants, and objectives are addressed.

Given our recent research²¹, we anticipate developing an implementation strategy consisting of (but not limited to): 1) staff trainings; 2) program champions; and 3) a positive reinforcement system. The trainings will target staff knowledge, buy-in, self-efficacy, and how to create/use a motor lab in a low resource environment. The program champion will help reduce teacher burden by maintaining the motor lab and providing ready-to-use lessons.²² The reinforcement system will target leadership support and culture. Overall, the implementation strategy will be designed to reduce existing barriers and provide ongoing support for teachers to maintain the use of active learning approaches.

As an initial step, we will establish a planning group that will consist of teachers, school staff, school wellness professionals, and parents. The group will also include wellness leaders from other school districts to help ensure the strategy is generalizable. The group will work with the research team throughout the project and will help develop the implementation strategy. IM will also guide the use of theory and empirical evidence to identify: 1) implementers of active learning; 2) the behaviors implementers must perform (performance objectives); and 3) the determinants that influence these behaviors. We will draw on our preliminary studies, existing literature, and input from the planning group. The duration of the implementation strategy planning/development phase is expected to be 1 year.

For phase 2 (aim 2) we will conduct a feasibility study to determine whether the implementation strategy is appropriate for further testing.²³ Our feasibility study will include acceptability and preliminary effectiveness testing, which are common for these types of studies.²³ Our study is designed to determine: 1) whether using an implementation strategy *can* improve the delivery of active learning in schools; and 2) whether there is evidence active learning *will* increase students' physical activity. By concurrently testing the implementation strategy *and* the effectiveness of active learning, we are using an approach known as a Hybrid Type 2 design.²⁴ Hybrid designs are unique to implementation research given their dual focus on implementation and effectiveness.²⁴ Hybrid Type 2 designs in particular, place equal emphasis on implementation and effectiveness outcomes. Thus, the primary study outcomes are: acceptability of active learning, implementation fidelity, and children's physical activity levels. Additional study outcomes include implementation quality and adherence, teacher acceptability of the implementation strategy, student's health related fitness, behavior, and academic performance. Data for some of the additional outcomes will be collected by schools.

For the feasibility study, we will use a quasi-experimental pre-post design in two elementary schools: one school will be randomly selected to receive the developed implementation strategy, while the other will serve as a comparison school and receive usual implementation support. We will use a concurrent mixed methods approach to examine study outcomes.²⁵ More specifically, we will collect

qualitative and quantitative data to triangulate findings. The duration of the feasibility study phase is expected to be one to two years (schools involved for 2 years and teachers/students involved for 1-2 years).

Study Population

Participating schools are expected to have about 40-45 teachers who will be recruited for this study. Teachers will be eligible if they are a lead teacher of an elementary classroom at a participating school. When recruiting teachers, we will make clear that participation does not require implementing active learning approaches. Rather, participation will entail completing baseline, 6-, and 12-month assessments along with implementation logs throughout the study. Teachers will receive a \$40 gift card for completing assessments at each time point and implementation logs. A subsample of about 30 teachers and school staff (e.g., instructional coaches, administrators) will be recruited to participate in semi-structured individual or group interviews to further examine acceptability and their opinions about active learning during the first follow-up assessment. We will recruit another subsample of about 20 teachers and school staff to participate in individual or group interviews to examine their perspectives of acceptability and active learning at the time of the second follow-up. For this second follow-up subsample, we will reconsent any teachers who participated in the first interview. We will use purposeful sampling by recruiting teachers from each grade (K-5) and school staff involved in supporting implementation efforts. Interview participants will receive a \$30 gift card for interview participation.

Students will be recruited from each school to examine student-level outcomes. All students will be eligible to participate unless they are unable to speak English or Spanish. For recruitment, study staff will conduct in-person presentations to students and staff to explain procedures and distribute recruitment materials. Each student will receive a permission packet consisting of a parent information sheet and a plain language consent form. The permission packet will be sent home with students and parents will be asked to sign the consent form and return it to the school if they agree to have their child participate in the study. After returning consent forms, study staff will obtain assent from students at school. We will use recruitment incentives (e.g., pencils for students, a project t-shirt for teachers) if 80% of students return their consent forms from a respective class. A subsample of 100 students at each school will be randomly selected to examine physical activity levels using a stratified sampling method based on grade and classroom. In addition, a subsample of about 30 students will also be recruited to participate in a semi-structured individual or group interview to examine the acceptability of active learning and learn more about physical activity from the student perspective. We will use a purposeful sampling method to recruit boys and girls, from grades (K-5). We will also work with teachers to help identify potential students across varying levels of engagement in active learning. Students who participate in an interview will receive a small toy of about \$10 in value (e.g., a pop-it or fidget spinner). Students who choose not to participate will attend school/class as usual. There will be no data collection for these students and thus their information will not be used in the study. They will be able to participate in the classroom activities provided by the teachers, which may include physically active breaks, time in the motor lab, or other active learning activities.

Study Procedures

The study will consist of a baseline assessment and two follow-up assessments: 6-month and 12-months. There will be multiple forms of data collection including paper and pencil surveys for students, electronic surveys for teachers, implementation logs, direct observation, objective physical activity

assessment (using accelerometers), the use of existing district data, and qualitative interviews. Table 1 provides an overview of variables, the method of assessment, and the collection time point.

Table 1: Data Collection (B=Baseline; F/U= 6- & 12-Month Follow-ups)		
Variables	Assessment Method	Time
Primary Study Outcomes		
Acceptability of Active Learning	Teacher Surveys	B and F/U
Implementation Fidelity (dose)	Teacher Survey and Implementation log	B and F/U
Student Physical Activity	Accelerometers	B and F/U
Additional Study Outcomes		
Health Fitness Outcomes	FitnessGram (collected by schools)	F/U
Academic Performance	Test Scores (collected by schools)	B and F/U
Student Behavior	Office referrals (collected by schools)	B and F/U
Implementation Fidelity (quality and adherence)	Teacher Surveys and Classroom observations	F/U
Acceptability of implementation strategy	Teacher interviews and surveys	F/U
Acceptability of active learning	Student Questionnaires	B and F/U
Additional Variables		
Demographics	Teacher Survey, Student data from district	B
CFIR and SCT constructs	Teacher Survey	B and F/U

We will use Qualtrics (a secure data collection tool) to distribute the electronic survey link to teachers. School district data (FitnessGram, academic scores, student behavior, and student demographics) will be transferred using SecureStor, which is a cloud-based storage application that is approved for storage of HIPAA and FERPA information at UTHealth, and thus provides a secure method for data sharing.

Qualitative data collection will consist of semi-structured individual or group interviews with teachers/staff and students beginning around the 6-month follow-up assessment. We will also conduct teacher/staff interviews at the 12-month follow-up assessment. Teacher/staff interviews will last 45-60 minutes, while student interviews will last about 30 minutes. All interviews will be recorded and transcribed for analyses. We will conduct separate thematic content analyses for student and teacher/staff interviews using iterative and deductive codes.²⁶⁻²⁹ Two coders will independently review and open code interview transcripts to identify prominent themes related to acceptability and other topics discussed in interviews.

Data collection for Primary Study Outcomes

Acceptability is the perception that an intervention is agreeable, feasible, or satisfactory to intervention recipients and implementers.³⁰ We will use the Acceptability of Implementation Measure (AIM)³¹, to examine acceptability of active learning among teachers. Data from the AIM will be collected as part of teacher surveys administered at baseline, 6- and 12-month follow-ups.

Fidelity will serve as a primary implementation outcome. Fidelity is the degree to which an approach was implemented as prescribed and is typically measured in terms of adherence, dose of delivery, and

quality of delivery.³⁰ Our primary fidelity outcome will be dose of delivery. We will use self-reported implementation logs and self-report surveys to assess dose.³³ Implementation logs will be completed weekly throughout the study.

Physical activity will serve as the effectiveness outcome to examine active learning at baseline, 6-, and 12-month follow-ups. We will use Actigraph GT3X+ accelerometers to examine minutes spent in moderate and vigorous physical activity. Accelerometers will be worn on an elastic belt placed above the iliac crest of the hip of each participant.^{34,35} Each belt will be attached to students within 30 minutes of the start of school and removed within 30 minutes of dismissal. Children will wear accelerometers for 5 consecutive school days, which meets minimum reliability recommendations.^{36,37} Each school will have 1-2 weeks of accelerometer data collection where we will assess 50-100 students/week. Research staff and trained parent volunteers will ensure accelerometers are properly placed and removed each day. Parent volunteers will receive a \$10 gift card for each day they help with the study.

Data Collection for Additional Study Outcomes (and additional variables)

Health-related fitness variables will be used from the mandatory FitnessGram assessments. FitnessGram testing occurs annually and is completed for students in grades 3-5. We will use data collected during the study year and the previous year to serve as a baseline measure. We will examine body mass index (from height and weight measures), aerobic capacity (from the 20-m PACER test), muscular strength and endurance (from push-ups and curl ups tests), and flexibility (measured by a sit and reach test).³⁸ Academic performance and student behavior will be additional outcomes given the district's high level of interest. The district will share relevant academic and student behavior data. In addition, publicly available data from the Texas Education Agency will be used to examine academic trends for schools.

Additional variables related to fidelity (i.e., quality and adherence) will also be assessed using the self-report survey and direct observation. Direct observation will be conducted by trained staff throughout the study. Staff will randomly select classrooms at different times of day to track implementation quality and adherence. Ratings will be based on: 1) how many children were active, 2) how often children were active, 3) the intensity of movement, and 4) adherence to core elements. We will also assess students' acceptability of classroom-based approaches and teachers' acceptability of the implementation strategy through survey questions and by conducting interviews.

Additional Variables: We will collect student demographic information (e.g., sex, age, race, qualifying for free/reduced cost lunch) from school records and student's self-reported physical activity data. We will also collect data from teachers (sex, age, race/ethnicity, number of years as a teacher, type of teacher, subject, physical activity level) and assess variables from implementation and health behavior theories and frameworks as part of the teacher survey. Examples of theoretical variables include culture, implementation climate, learning climate, leadership engagement, available resources, knowledge, skills, self-efficacy, attitudes, barriers, and outcome expectations.

Data and Safety Monitoring

Risks in this study are minimal but may include breaches of confidentiality and loss of time should participants not feel the study is relevant, although these are highly unlikely. The steps taken to reduce these risks include using UTHealth approved applications for sharing data and collecting consent (and assent from minors) prior to participation. We acknowledge that in addition to these risks, many unrelated and/or random adverse event may occur during the study period. All known related risks will be described in the consent form.

Dr. Walker is the PI and will be responsible for monitoring the safety environment of participants. Additional oversight will be provided by his mentors all of whom are experienced researchers. Dr. Walker will be responsible for monitoring procedures during the study for participants, including inclusion, enrollment, data collection, study outcomes, informed consent and assent in minors, and subject safety.

Proposed monitoring and safety review:

- a) Immediate reporting of adverse events by team members to Dr. Walker
- b) Quarterly review of data by Dr. Walker and mentorship team during data collection phase

Study data will be reviewed following each week of data collection during baseline and follow-up periods for each respective school by Dr. Walker. If an adverse event occurs, Dr. Walker and his mentors will determine whether the event requires reporting to the IRB, the school district's Research and Develop office, and to NIH.

Statistics

Quantitative Analysis Strategy: We will use generalized linear models to compare implementation fidelity and acceptability between teachers who received the strategy versus teachers who did not. Longitudinal/ repeated measures analyses will be conducted for student level variables using generalized linear multilevel modeling. Multilevel effects will address classroom clustering. Bayesian approaches will implement joint modeling of observed outcomes and missing data, which is robust to ignorable missingness.³⁹Sensitivity analyses will evaluate robustness of analytic conclusions to missing data. Convergence of Bayesian analyses on the posterior distributions via Monte-Carlo Markov chain will be assessed via graphical (Trace Plot, Autocorrelation Plot) and quantitative evidence (Gelman-Rubin Diagnostics and Effective Sample Size Diagnostics). Evaluation of posterior distributions will permit statements regarding the probability that effects of varying magnitudes exist, given the data. Specification of weak, neutral priors as well as the prior distribution for level two variances will follow recommendations by Gelman.^{40,41}The impact of the implementation strategy on implementation and student outcomes will be based on the posterior distribution of effect sizes.

Sample Size: Given this is a feasibility study, the study purpose is to examine acceptability and effectiveness trends. Thus, the study is not designed to statistically examine school level differences in implementation outcomes. The study will provide important descriptive data and inform future work. Our analytic approach, applying Bayesian methods, will result in a posterior distribution for the credible effect size analysis, importantly providing both an index of the effect size and its associated uncertainty. This posterior distribution will permit probabilistic estimates of the alternative hypothesis. Moreover, subsequent trial planning will incorporate the entire posterior, both its estimate and associated uncertainty in developing a robust plan for a subsequent R01 study.^{42,43}In addition, we will use the study information to calculate intraclass correlation coefficients at the teacher level to inform multilevel modeling in future studies.

Exploratory Analysis: Because Action-Based Learning is relatively new and other types of physical activity have differentially appealed to boys and girls^{44,45}, one important question is whether this approach is acceptable and effective for both sexes. Therefore, we will conduct an exploratory analysis examining acceptability and effectiveness trends between boys and girls. We will use approaches similar

to what have been previously described where gender will be entered into models as an additional interaction term.

Ethics

Teachers will be asked to complete a study consent prior to participation. The consent form will include information about completing an online survey, completing an implementation log, and agreeing to classroom observations. We will use a separate consent form for teachers/staff who are also interested in participating in an individual or group interview. We will provide teachers/staff with the option of participating in an in-person interview or a virtual interview using a program such as Webex or Microsoft teams. For teachers/staff who prefer to do a virtual interview, we will use a waiver of documentation of consent.

We will obtain consent and assent for each student. Students will bring a permission packet home from school that will consist of a parent information sheet and a plain language consent form. After students return their consent form, study staff will obtain assent from students. The packets will be distributed to students' families through weekly folders and other school-based events.

Data handling and record keeping

All collected data will be processed, analyzed, and stored on UTHealth School of Public Health's dedicated secure server. Data will be recorded on UTSPH secure servers where only study staff will have password protected access to the study records.

Surveys, implementation logs, and classroom observation data: Because some data from teachers will be collected through an electronic survey distributed through an email link, respondent information will be collected such as IP and email addresses. However, no other identifying or protected health information will be collected from electronic surveys. Hardcopies of data (e.g., student surveys, implementation logs, classroom observation forms, qualitative interview notes) will be stored in locked cabinets with limited key access. Each participant will receive a unique study identification number, which will be used to label data files. This study identification number will also be used to link study data from different sources.

Interview data: All interviews will be recorded and transcribed. Transcriptions will be edited to exclude names and other identifying information. Audio and transcription files will be stored on UTHealth's secure server. Demographic information (e.g., age and gender) will be collected from interview participants using a separate demographic questionnaire. This questionnaire will not include participant names and will only be used to describe the interview sample in aggregate form.

Other Study Data and Information: Accelerometer data will be stored on UTHealth's secure server for each student using a study identification number. Health fitness and academic performance data collected by the district will be shared using SecureStor, a cloud-based application that is approved for storage of HIPAA and FERPA information at UTHealth. In addition, other identifying information (e.g. consent forms, study identification linking file) will be stored in locked cabinets separate from study data.

Data handling procedures will be overseen by Dr. Walker with the guidance of the mentoring committee.

Publication Plan

We will use an approach informed by designing for dissemination (D4D) principles to communicate findings.⁴⁶ D4D acknowledges that different audiences require specific messaging and communication channels.⁴⁶⁻⁴⁸ Thus, we will use our planning group to determine relevant findings for *practitioners* and identify dissemination opportunities. We will reach the *community* by writing 1-2-page briefs with infographics for district leaders and presenting at senior leader and staff meetings. We will reach *Practitioners* through local and national meetings (e.g. kinesthetic classroom collaborative, the American School Health Association Conference). We will also publish findings in practice-oriented journals. We will reach *researchers* in numerous fields (e.g. implementation science, physical activity) through publications in high-impact, peer-reviewed journals and research meetings such as the Dissemination and Implementation Conference.

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