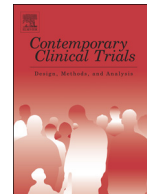




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# Making healthy eating and physical activity policy practice: The design and overview of a group randomized controlled trial in afterschool programs

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## ABSTRACT

National and state organizations have developed policies calling upon afterschool programs (ASPs, 3–6 pm) to serve a fruit or vegetable (FV) each day for snack, while eliminating foods and beverages high in added-sugars, and to ensure children accumulate a minimum of 30 min/d of moderate-to-vigorous physical activity (MVPA). Few efficacious and cost-effective strategies exist to assist ASP providers in achieving these important public health goals. This paper reports on the design and conceptual framework of Making Healthy Eating and Physical Activity (HEPA) Policy Practice in ASPs, a 3-year group randomized controlled trial testing the effectiveness of strategies designed to improve snacks served and increase MVPA in children attending community-based ASPs. Twenty ASPs, serving over 1800 children (6–12 years) will be enrolled and match-paired based on enrollment size, average daily min/d MVPA, and days/week FV served, with ASPs randomized after baseline data collection to immediate intervention or a 1-year delayed group. The framework employed, STEPs (Strategies To Enhance Practice), focuses on intentional programming of HEPA in each ASPs' daily schedule, and includes a grocery store partnership to reduce price barriers to purchasing FV, professional development training to promote physical activity to develop core physical activity competencies, as well as ongoing technical support/assistance. Primary outcome measures include children's accelerometry-derived MVPA and time spend sedentary while attending an ASP, direct observation of staff HEPA promoting and inhibiting behaviors, types of snacks served, and child consumption of snacks, as well as, cost of snacks via receipts and detailed accounting of intervention delivery costs to estimate cost-effectiveness.

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## Q3 1. Introduction

Across the nation, afterschool programs (ASPs) serve more than 8.4 million youth, the majority of which are elementary-age (6–12 years) [1]. Programs run every day of the school year, and start immediately following the end of the regular school schedule, lasting for an average of 3 hours each day [2]. This widespread reach and length of contact has made

them a focus point of childhood obesity prevention efforts, in recent years. As part of their daily schedule, ASPs offer a snack and opportunities for children to be physically active. Unfortunately, the snacks served in ASPs are characterized as high in sugar, salt, and/or fat, and are almost devoid of fruits or vegetables [3–7], whereas the amount of physical activity children accumulate falls well below existing policy standards [8–10].

To address this gap between policy and practice, both state and national organizations have developed, adopted, or endorsed policies outlining the nutritional quality of snacks

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served and the amount of physical activity children should accumulate while attending an ASP [11,12]. While such policies are necessary and have the potential to make a major contribution to children's total daily healthy eating and physical activity (HEPA), there are few effective and scalable strategies ASP providers can use to meet the HEPA policies [2,5,13–21]. Previous interventions targeting healthy eating, physical activity, or both within the ASP setting have had mixed results. Policy-focused interventions [3,6] have shown that substantial changes in the quality of snacks served can be achieved from adopting a policy that defines the types of snacks ASPs should serve. However, these studies have failed to address a major barrier in serving healthier snacks—cost [21–24]. Another study [5,14] did not make changes in the quality of snacks served, with this largely due to cost and the lack of priority of serving a more healthful snack, like a fruit or vegetable. Three physical activity interventions in the ASP setting have reported modest increases in physical activity through the use of pre-packaged curricula [5,13,17]. However, five studies reported that pre-packaged curricula do not increase children's physical activity compared to ASPs not using the curricula [14–16,18,20]. Moreover, pre-packaged curricula can be costly [25] or contain a large number of unfamiliar games that are difficult for unskilled staff to play [20]. Moreover, no physical activity interventions in the ASP setting have explicitly investigated the impact on clearly defined policy goals.

This paper describes the study design and conceptual approach of a large scale group randomized controlled trial, Making HEPA Policy Practice. The goal of this study is to evaluate the effectiveness of HEPA strategies, which consist of a multi-step, adaptive intervention [26] approach, that addresses price barriers to serving more healthful snacks and professional development training to develop core competencies to promote physical activity to meet the NAA Healthy Eating Standards and the California After School Resource Center Physical Activity Guidelines. Additionally, detailed information on the delivery of intervention will be collected to estimate cost-effectiveness.

## 2. Methods

### 2.1. Study design

The study was designed and will be reported according to the CONSORT guidelines for cluster randomized controlled trials.

A total of 20 ASPs (cluster/group level) will be randomly selected and recruited fall 2012 from a pre-existing list of 535 program providers within a 1.5 hour drive of the university. The list was provided by a state-level organization responsible for policy and resources for ASPs. For this study, ASPs are defined as child care programs operating immediately after the school day, every day of the school year for a minimum of 2 hours, serving a minimum of 30 children of elementary age (6–12 years), operating in a school, community, or faith setting, and providing a snack, homework assistance and completion time, enrichment (e.g., arts-n-crafts), and opportunities for physical activity [25]. Programs that are singularly focused (e.g., dance, tutoring) and/or physical activity focused (e.g., sports, activity clubs), are not eligible for participation. We will measure the physical activity

of at least 1300 children enrolled across the 20 ASPs (65 per ASP). All children enrolled, staff, and ASP leaders in the ASPs are eligible to participate in the study. The only exclusion criterion for children to take part in the physical activity assessment (i.e., accelerometry) is the inability to be physically active without an assistive device (e.g., wheel chair, crutches). No other exclusion criteria will be imposed on any of the study procedures.

The design is a repeated cross-sectional group randomized controlled trial with a delayed treatment group. This design is appropriate when outcomes are tracked at a group level (e.g., ASPs), instead of at the individual level (e.g., children) [27,28] and is consistent with recent large scale trials of site-level interventions for children and adolescents [5,29–33]. The study will take place over 3 years, with 1 year of baseline (i.e., year 1), and 2 years of intervention (i.e., year 2 and 3). The 20 ASPs will be randomized into one of two conditions: 1) immediate HEPA strategies or 2) 1-year delayed group. The immediate intervention group will receive the HEPA strategies (outline below) over 2 years (i.e., years 2 and 3), while the delayed group will receive the HEPA strategies during the last year (i.e., year 3) of the study. This design allows for the testing of the effects of the HEPA strategies compared to routine practice (i.e., between group differences from baseline to end of year 2 of the intervention) and the additional improvements achieved in HEPA from receiving 1 vs. 2 years of the intervention (i.e., between group differences from baseline to end of year 3 of the intervention). All outcomes will be modeled and expressed as changes occurring at the ASP level—the unit of randomization.

All measures will occur during the spring of each year. Across the study, we anticipate that 24% of the children will leave the participating ASPs each year for reasons unrelated to the study (e.g., family relocating, transitioning from elementary to middle school). Further, based on our pilot work [34] we anticipate that almost two thirds of the children will be present at two of the three measurement occasions and that an adventitious cohort of ~30% of the children will be present at all 3 measurements.

### 2.2. Informed consent

Each ASP will provide parents information on the nature of the study and the child level measurements (physical activity and height and weight) to be collected, prior to enrolling a child in the ASP. Parents will be able to opt their child out of participation in the child-level assessment. A detailed list of these parents will be maintained by the ASP and provided to research staff prior to data collection. Each eligible child will be asked to verbally assent in front of ASP and research staff to participating in the data collection. Additionally, information regarding the study will be placed in parent handbooks, signup pamphlets, and posted on the ASPs' websites.

### 2.3. Randomization and pair matching

Randomization of the 20 ASPs to immediate ( $n = 10$ ) vs. delayed treatment ( $n = 10$ ) groups will be performed after baseline data collection, summer 2013, using a random number generator. Programs will be match-paired based on enrollment size, average levels of MVPA/d, and number of days per week (out of a 5 day week) a FV is served. Enrollment size will be

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