# Examples of Funded Grants in Implementation Science

### Overview

The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let Implementation Science (IS) post excerpts of their dissemination and implementation (D&I) grant applications online.

### About

We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. In addition, we only include a copy of SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches).

### Copyright Information



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# 424 R&R and PHS-398 Specific

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# SF 424 R&R Face Page

**PI:** Lee, Rebekka Mairghread

**Grant Number:** 1 R21 CA201567-01A1

**Title:** Effective Training Models for Implementing Health-Promoting Practices Afterschool

**FOA:** PAR13-054

**FOA Title:** DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH (R21)

**Organization:** HARVARD SCHOOL OF PUBLIC HEALTH

**Department:** Social and Behavioral Sciences

**Senior/Key Personnel:** Rebekka Lee

**Organization:** President and Fellows of Harvard College

**Role Category:** PD/PI

## Project Summary

Over the past two decades, excess dietary intake and low physical activity have contributed to an increase in the prevalence of childhood obesity in the United States, affecting a third of children and disproportionately impacting minority and economically disadvantaged children. Given that obesity is a risk factor for health outcomes later in life, including cancer, early obesity prevention efforts are critical for population health. Out-of-school time (OST) programs are an important setting for addressing childhood obesity given that 10.2 million U.S. children are enrolled in afterschool. The Out-of-school Nutrition and Physical Activity (OSNAP) group-randomized trial demonstrated improvements in children's vigorous physical activity, the healthfulness of foods and beverages served and consumed, and health- promoting program policies. Now that the OSNAP intervention has been rigorously tested and effectiveness has been established, there is a *critical need* to evaluate training models to disseminate this intervention for broad population reach and impact. Our *long-term goal* is to investigate the implementation and dissemination of evidence-based prevention interventions in OST settings. The *overall objective* of this proposal is to establish the effectiveness of two existing training models for scaling up the OSNAP intervention and understand the influence of context on effective implementation. In collaboration with the YMCA, we will conduct a 3-arm group randomized trial to compare two methods of delivering the learning collaborative with a control group. This application addresses the following *specific aims:*

1. ***Compare the effectiveness and implementation cost of two learning collaborative training models for the OSNAP intervention.*** We hypothesize that both training models will produce healthy changes in OST nutrition and physical activity practices as measured by a validated observational assessment, compared to the control group. Secondary outcomes of specific healthy practices, such as offerings of physical activity and water, and process outcomes, such as cost and acceptability, will vary by training model.
2. ***Use mixed methods to identify actionable factors within the implementation context that influence the effectiveness of the OSNAP intervention delivered by two learning collaborative training models.*** We hypothesize that programs with more supportive implementation contexts will more effectively implement OSNAP than programs with less supportive contexts. Qualitative data will help *explain how* aspects of the implementation context influence effective implementation of each training model in greater depth.

## Project Narrative

This project proposes an investigation of two training models for scaling up an evidence-based afterschool nutrition and physical activity intervention. The proposed research project, a group randomized trial, is relevant to public health as it seeks to address the nation's high childhood obesity rates by establishing the effectiveness and implementation of in person and online trainings. Upon completion, researchers and afterschool leaders will be able to identify effective training models for working with diverse programs to reach the 10.2 million children served by US afterschool programs and better understand the afterschool setting for situating future childhood prevention interventions.

## Specific Aims

Over the past two decades, excess dietary intake and low physical activity have contributed to an increase in the prevalence of childhood obesity in the United States, affecting a third of children and disproportionately impacting minority and economically disadvantaged children. (1-3) Given that obesity is a risk factor for health outcomes later in life, including cancer (4, 5), early obesity prevention efforts are critical for population health. (3) Out-of-school time (OST) programs are an important setting for addressing childhood obesity given that 10.2 million U.S. children are enrolled in afterschool. (3, 6) Moreover, OST settings have the potential to address disparities; the highest afterschool participation rates are among low income, African-American, and Latino children. (7) Evidence for OST nutrition and physical activity interventions has grown in recent years; (8-13) the Out-of-school Nutrition and Physical Activity (OSNAP) group-randomized trial recently demonstrated improvements in: children's vigorous physical activity (14), the healthfulness of foods and beverages served (15) and consumed (16, 17), and health-promoting program policies. (18) OSNAP is a multilevel learning collaborative intervention designed to build the skills and knowledge of OST staff for creating health-promoting policy and practice changes. Over one school year, teams set data-driven action plans around 10 health goals and share implementation experiences. Now that the OSNAP intervention has been rigorously tested and effectiveness has been established, there is a *critical need* to evaluate training models to disseminate this intervention for broad population reach and impact.

Our *long-term goal* is to investigate the implementation and dissemination of evidence-based prevention interventions in OST settings. The *overall objective* is to establish the effectiveness of two existing training models for scaling up the OSNAP intervention and understand the influence of context on effective implementation. In collaboration with the YMCA and following the Consolidated Framework for Implementation Research (CFIR) (19), we will conduct a 3-arm group randomized trial to compare two methods of delivering the learning collaborative with a control group. *Our central hypothesis* is that both a facilitated, online training and an in-person training delivered via a train-the-trainer model will produce healthy changes compared to the control group. We seek to test an online training, given its potential to reach a geographically dispersed, largely part-time and low-wage workforce at a lower cost and with greater flexibility than traditional in-person models. The proposal will explore how implementation outcomes (20), such as cost and acceptability, and contextual influences, such as organizational resources, differ and influence the effectiveness of each training type. Our *rationale* for this proposal is that identifying effective training models will help to scale up OSNAP to improve the nutrition and physical activity of the millions of children served by OST programs each day. The primary outcome is an aggregate healthy practice score derived from a validated observational measure. (21) Secondary outcomes are items from the aggregate score including: offerings of physical activity, screentime, fruits and vegetables, water, juice, whole grains, and sugary drinks from outside the program. Process outcomes include cost, reach, fidelity, feasibility, acceptability, and adaptability. Qualitative and quantitative data on the implementation context (e.g. inner setting, outer setting, and characteristics of individuals) will also be collected. This application addresses the following *specific aims:*

***1. Compare the effectiveness and implementation cost of two learning collaborative training models for the OSNAP intervention.*** We hypothesize that both training models will produce healthy changes in the OST nutrition and physical activity environment, compared to the control group. Secondary outcomes of specific healthy practices and process outcomes, such as cost, will vary by training model.

**2. *Use mixed methods to identify actionable factors within the implementation context that influence the effectiveness of the OSNAP intervention delivered by two learning collaborative training models.*** We hypothesize that programs with more supportive implementation contexts will more effectively implement OSNAP than programs with less supportive contexts. Qualitative data will help *explain how* aspects of the implementation context influence effective implementation of each training model in greater depth.

We anticipate the following ***expected outcomes.*** First, we will establish the effectiveness of two training models and determine the "best buy" for future dissemination. Next, we will describe actionable aspects of the OST implementation context that influence the uptake of OSNAP and can be incorporated into the design of future training models for maximum impact. These outcomes are expected to have a ***positive impact*** as they will identify effective training models for working with diverse OST programs and staff to scale up for greater population reach and better understand the OST setting for situating future childhood prevention interventions.

## Research Strategy

Our team is poised for a successful grant, with a combined 32 person-years collaborating with OST partners to investigate nutrition and physical activity promotion. Although junior in position, Dr. Lee has demonstrated experience to lead this research. She has worked for a decade, beginning as a research assistant and progressing to doctoral work and project leadership, to conduct rigorous group randomized trials and driving our team to expand its program of research to include dissemination and implementation science.

### Significance

Over one third of U.S. children are currently overweight or obese, with higher rates among children of color and those of lower socioeconomic status. (1) Excess dietary intake is strongly linked to childhood obesity via caloric imbalance (22), particularly driven by sugary beverages. (23-25) There is also strong evidence that physical activity is a driver of obesity among children. (26, 27) Broad-based dissemination of evidence-based obesity prevention interventions in OST settings, like the rigorously tested OSNAP intervention (14-18), could have a significant impact on population health and the reduction of health disparities given the large reach of afterschool programming to over 10.2 million U.S. children for an average of seven hours each week (6) and the high rates of participation among low income, African-American, and Latino children. (7) The contribution of the proposed research is expected to be the identification of an effective, low cost training model for disseminating an evidence-based intervention for improving child nutrition and physical activity. *This contribution is significant because it promotes the dissemination of an intervention that has proven successful in improving health behaviors that are strongly linked to childhood obesity morbidity and health outcomes, such as cancer, later in life. Moreover, the proposed research aligns with the National Institutes of Health's mission to identify, evaluate, and refine effective and efficient strategies to disseminate and implement research tested prevention interventions into public health settings.*

### Innovation

- *The proposed research is innovative because it seeks to test training models for implementing policy and organizational changes in a community setting.* This contrasts with typical nutrition and physical activity trainings that focus on individual behavior change through health education. To date, dissemination and implementation research has been focused largely in the clinical setting (28) with much attention focused on identifying implementation barriers. (29) We aim to take a prevention, population-based focus that emphasizes solutions over challenges. Given the potential reach of OST (6), where the average attendee spends 260 hours each year, the setting is an understudied context to promote population health.

- *This proposal seeks to build on the growing evidence for the effectiveness* (30) *and lower transactional cost* (31) *of online interactive learning* that has led to a substantial shift in education and workforce training in recent years, (32), yet has had limited application to community health interventions, by testing the impact of a facilitated, online learning community. We will test a self-paced, low-cost online training model with interactive activities and discussion boards, which holds tremendous potential for broad-reaching, sustainable training given the largely part-time OST workforce. (33)

- *This study moves away from a one-size-fits-all approach by investigating the underlying mechanisms and contextual factors that influence successful implementation in real-world settings.* It seeks to identity how training models may differ in their ability to achieve specific practice and implementation outcomes. Following CFIR, this study will identify actionable factors within intervention characteristics (e.g. complexity, design quality and packaging, cost), the outer setting (e.g. external policies), the inner setting (e.g. resources and norms in the organization), and characteristics of individuals (e.g. knowledge and beliefs, experience) that influence success. (19) Given the high turnover, low wage nature of the OST sector, (33) this emphasis on understanding contextual influences of successful implementation of an evidence-based prevention intervention is critical.

- Finally, this research employs an explanatory sequential mixed methods design (34) and novel, validated measures (21, 35, 36) for a comprehensive understanding of the success of each OST training model.

*This proposal is innovative because it uses an advanced mixed methods design and novel measures to comprehensively investigate training models in a unique community setting where potential population health impact is significant.*

# Research Approach

**Aim 1: Compare the effectiveness of two learning collaborative training models (e.g. in-person train-the-trainer vs. facilitated online) for the OSNAP intervention.**

***Introduction.*** Studies have demonstrated the effectiveness of OST-based nutrition and physical activity interventions; however, there remains a critical need to evaluate training models for spreading these evidence-based strategies to real-world settings. The *objective of this aim* is to establish the effectiveness of two existing learning collaborative training models designed to build the skills and knowledge of OST staff for creating policy and practice changes around the following OSNAP goals: ban sugar-sweetened drinks from snacks served and brought in from outside the snack program; offer water as a drink at snack every day; offer a fruit or vegetable option every day at snack; ban foods with *trans* fats from snacks served; serve whole grains; offer 30 minutes of physical activity to all children daily; offer 20 minutes of vigorous physical activity to all children 3 times per week; and eliminate television, movies, and non-educational screentime. To attain this objective, we will test the working hypothesis that both training models will produce changes in OST nutrition and physical activity environment compared to controls. We will also investigate whether secondary outcomes of specific OSNAP goals and process outcomes, such as cost and feasibility, vary by training model. For instance, water and physical activity outcomes may be similarly amenable to change with both training models, while more complex outcomes such as fruits and vegetables or whole grains may require more hands-on interaction with the in-person train-the-trainer model. Similarly, implementation outcomes could vary: acceptability may be higher for the in-person training because this is the standard mode in the field and fidelity may be higher for the online training because it will be more closely controlled. By comparing outcomes before and after the intervention, we will be able to identify whether one or both of the training models are effective for creating healthier OST environments. When aim 1 has been completed, we will be able to identify whether the training models had differential impacts on specific nutrition, physical activity, and implementation outcomes. Such a finding would allow practitioners to choose the training model that best addresses the practice gaps in their setting and pinpoint areas for refinement of the OSNAP training model prior to large-scale dissemination.

**Justification and Feasibility**

**Review of Relevant Literature.** Although experts have established evidence-based standards on *what* nutrition and physical activity goals should be promoted in OST settings (37, 38), there is limited research on *how* best to provide ongoing, comprehensive training to OST staff on implementing health-promoting practices and policies. OST professional development, which is important for youth outcomes and the sustainability of the workforce, varies according to program characteristics and provider needs, but the effectiveness of training models, including distance learning, has not been well evaluated. (39) This proposal seeks to determine how to scale up a learning collaborative approach (40), which has shown promise in OST settings (41), for a broader, more sustained reach through a train-the-trainer model and an interactive, online training—two training models with strong evidence for success. The train-the-trainer approach has proven successful for evidence-based practices ranging from improving breast feeding rates (42) to increasing motivational interviewing skills. (43) Research has shown similar effects for online and face-to-face learning (30) and emphasizes that consistency of course design, contact with instructors, and active discussion are important for online learning success. (44) Notably, a randomized trial comparing in person and online trainings for obesity prevention in childcare settings found similar knowledge change for both training models (45) and childcare managers report high intensions to use Web-based nutrition and physical activity programs. (46) With lower transactional costs and self-paced formats, online platforms such as massive open online courses have had great appeal and widespread use in education and workforce development. (31) This review of the relevant literature demonstrates that evaluating online and in person training models for implementation of an evidence-based OST learning collaborative will be a valuable contribution to the implementation and dissemination science field.

**Preliminary studies.** The experiences described below support the feasibility of our team's ability to achieve the objectives set forth in aim #1. This includes: 1) the decade of research we have conducted in the OST setting, 2) our unique expertise collecting implementation cost data, 3) the comprehensive trainings and resources we have developed for OST providers, and 4) the strong partnership we have with the YMCA. Recently, our team designed the OSNAP learning collaborative intervention and tested its effectiveness in an 8-month group randomized controlled trial. Participation in OSNAP was associated with significant increases in snack (+2.6, p=0.003), beverage (+2.3, p=0.008), and screen time (+0.8, p=0.046) policies. (18) Participants in

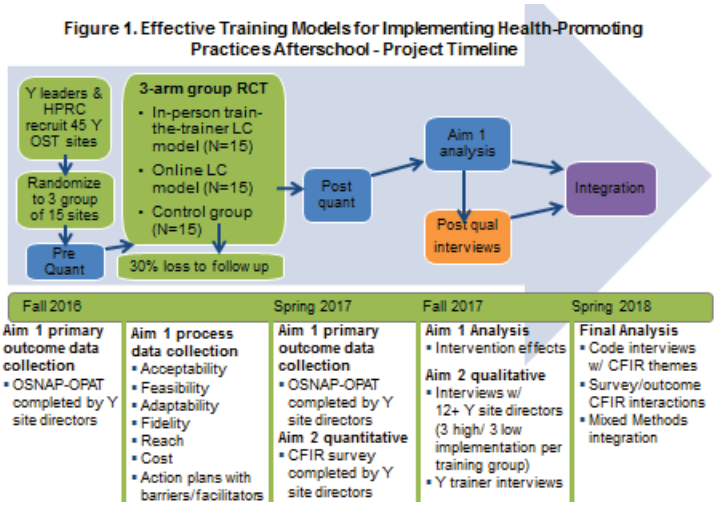
intervention programs had a 57% increase in minutes/day in bouts of vigorous physical activity (+4.1, 95% CI 2.7-5.5; p<0.0001) during program time, relative to controls. (14) The intervention also successfully improved children's dietary intake during snack. (Table 1) (16, 17) Since demonstrating effectiveness in the OSNAP trial, we have collaborated with city government, school, and YMCA partners to spread OSNAP to 136 sites in Massachusetts. Local dissemination has used an in-person train-the-trainer model with outcomes measured by the Out-of-School Nutrition and Physical Activity Observational Practice Assessment Tool (OSNAP-OPAT), a low-cost measure of program practices with correlations ranging from 0.56 to 0.85 when compared with accelerometry and direct observation of dietary intake. (21) Changes in the aggregate OSNAP-OPAT score from 36 sites indicate that, on average, sites achieved 1.42 additional OSNAP weekly goals after participation in the 8-month intervention (p<0.01). Our team also has extensive experience collecting the process outcomes proposed, particularly precise measures of implementation cost and reach, which are instrumental to our CHildhood Obesity Intervention Cost-Effectiveness Study (CHOICES). A core component of CHOICES is assessing and comparing implementation costs (scaled to local, state, and national levels) of evidence-based interventions. CHOICES costing methods are based on standard economic approaches (47, 48), established guidelines (49), and our team's experience assessing the costs of implementing physical activity and nutrition policies and programs. (50-52) Materials we developed during the trial—including a policy writing guide, decision aids, and training slides—have been packaged with feedback from OST staff and are available for free at www.osnap.org. In fall 2014, we launched our online learning collaborative platform, which consists of video clips, activities, and a discussion board facilitated by the HPRC for OST staff to brainstorm and network. We have worked with our YMCA partners to pilot this online training to establish its usability and acceptability; no major changes have been identified. These preliminary data and decade-long YMCA partnership are important in establishing the feasibility of our first aim as they exemplify our team's capacity to conduct rigorous research in real world settings and in close collaboration with partners. Furthermore, our work developing and piloting the in person and online trainings show that we are ready to "hit the ground running" to implement this study.

**Table 1. OSNAP RCT impact on daily snack consumption (N=400)**

| | Baseline | Follow-up | Adjusted Change | |
|---|---|---|---|---|
| | Mean (SE) | Mean (SE) | Beta | P value |
| **Ounces of water** | | | | |
| Control | 0.16 (0.05) | 0.10 (0.03) | -- | |
| Intervention | 0.28 (0.05) | 1.71 (0.16) | 1.49 | <0.0001 |
| **Ounces of juice** | | | | |
| Control | 1.88 (0.12) | 2.22 (0.17) | -- | |
| Intervention | 1.57 (0.12) | 1.34 (0.12) | -0.61 | 0.02 |
| **Servings of trans fat foods** | | | | |
| Control | 0.05 (0.01) | 0.09 (0.02) | -- | |
| Intervention | 0.20 (0.02) | 0.12 (0.02) | -0.12 | 0.002 |
| **Servings of whole grains** | | | | |
| Control | 0.19 (0.02) | 0.13 (0.02) | -- | |
| Intervention | 0.15 (0.02) | 0.19 (0.02) | 0.10 | 0.02 |
| **Calories** | | | | |
| Control | 138.0 (5.2) | 139.6 (5.0) | -- | |
| Intervention | 158.8 (6.6) | 112.6 (4.9) | -47.8 | <0.0001 |

***Research Design.*** **The project will utilize a 3-arm group-randomized control trial** to establish the effectiveness of two learning collaborative training models (e.g. train-the-trainer in-person vs. online) for an evidence-based OST nutrition and physical activity intervention (Figure 1). We will compare sites that receive the training models with a control group (controls will receive OSNAP training after the effectiveness trial is complete). We will work with YMCA leadership to recruit 45 demographically diverse YMCA OST sites from across the country. Sites will be matched on racial/ethnic composition, proportion of students eligible for free or reduced price meals, program enrollment, urban/rural/suburban setting, and physical activity and food service facilities available. One-third of the sites will be randomized to participate in the online training over the school year, one-third will participate in the in-person train-the-trainer model, and one-third will serve as controls. After randomization, in fall 2016, teams of YMCA OST directors and line staff will be invited to participate in the OSNAP learning collaborative trainings. The intervention follows the social ecological model (53) with activities targeting multiple levels of change—school district/program sponsor, OST site, interpersonal, and individual—and emphasizing on adoption of the following OSNAP goals: ban sugar-sweetened drinks from snacks served and brought in from outside the snack program; offer water as a drink at snack every day; offer a fruit or vegetable option every day at snack; ban foods with *trans* fats from snacks served; serve whole grains; offer 30 minutes of physical activity to all children daily; offer 20 minutes of vigorous physical activity to all children 3 times per week; and eliminate television, movies, and non-educational screentime. Sessions are designed consistent with the Institute for Healthcare Improvement Breakthrough Series Collaborative model (40) and use constructs from social cognitive theory—knowledge and skill development coupled with action planning—to drive environmental and behavior change. (54) Teams will use the OSNAP-OPAT (21), decision aids, policy writing guides, and other resources available at www.osnap.org to set data-driven goals and implement discrete practice, policy, and communication action steps throughout the year. Staff will also receive training on the *Food & Fun After School* curriculum available at foodandfun.org.

The **in-person model** will begin with a 6-hour train-the-trainer session led by HPRC researchers in August 2016 on OSNAP coordination, content, and facilitation skills for YMCA trainers. Trainers will then implement three 3-hour in-person learning sessions (in the fall, winter, and spring) and a 1-hour *Food and Fun* training with teams of YMCA sites in their geographic area throughout the 2016-2017 school year and conduct technical assistance between sessions via email and telephone. For the **online model**, content will be delivered via 7 short, self-paced sessions consisting of video clips and application activities. An online discussion forum with required dialogs facilitated by HPRC researchers will be used to help staff brainstorm and network with other OST sites, ensuring interactivity with instructors and peers that is key for online learning success. (44) For both training models, contact time is 10 hours and staff earn continuing education units.




Baseline data will be collected in fall 2016, with follow-up data collected in spring 2017 (6 months later). Effectiveness of the intervention will be measured with the OSNAP-OPAT—an observational measure of nutrition and physical activity practices that site staff complete for one week before and after the intervention. (21). Our team validated the tool with OST staff similar to those proposed to complete the measure in this study, establishing criterion validity for physical activity and nutrition outcomes with correlations ranging from 0.56 to 0.85 when compared with accelerometry and direct observation of dietary intake. Results indicated that program practitioners can assess OST program practices with accuracy and validity did not vary by the intervention status of the staff. For the primary outcome power calculation, an aggregate of validated OSNAP-OPAT items, we assume an average of 4 days data nested in each site will be completed at each time point. With 45 sites and a 66% retention rate, we anticipate 10 online, 10 in person, and 10 control sites with complete longitudinal data. Estimates for the effect size to be detected as statistically significant are based on OSNAP dissemination studies indicating a mean increase of 1.42 (baseline to follow up). Prior OSNAP results provide a sd=1.01, r (the within-site correlation between baseline and follow up)=0.5, and intraclass correlation=0.51. With these assumptions and 80% power, we will be able to detect an increase of one OSNAP goal in each training group arm, compared to controls. We do not anticipate significant differences between training models. Secondary outcomes will be specific items from the aggregate score: offerings of physical activity, screentime, fruits and vegetables, water, juice, whole grains, and sugary drinks from outside the program-provided snacks. We plan to validate the OSNAP-OPAT measure with direct observations by trained research assistants in a small sub-sample of sites from each training arm.

Additionally, we will measure the reach of each dissemination strategy with enrollment data and survey all participating YMCA site staff on acceptability, feasibility, and adaptability of the online and in-person learning collaborative models. (20) Costing will take a societal perspective; (49) data will be collected prospectively from sites according to our established CHOICES protocol (see Appendices). Staff will complete action plans, which track the practice, policy, and communication strategies they use to achieve the OSNAP goals and document the barriers and facilitators they encounter. They will self-report knowledge and skills after each learning session. Fidelity will be measured with automated completion metrics (online course) and observations (in-person training). High evaluation ratings and fidelity observations have been observed in local dissemination delivered by YMCA and health department trainers. YMCA trainers and sites will receive $200 stipends for participation. HPRC staff will work with YMCA leaders to ensure high retention.

***Expected outcomes.*** Aim 1 has a number of expected outcomes that will contribute toward the NIH goal of identifying, evaluating, and refining effective and efficient strategies to disseminate and implement research tested prevention interventions into public health settings. First, we expect to establish the effectiveness of two training models for the OSNAP intervention. Additionally, we will collect data on implementation outcomes such as feasibility and acceptability that help gauge *how* the training models work in practice and how much they cost. Bringing these effectiveness and implementation outcomes together, we will be able to identify how to use these training models to make the broadest population reach for improved child nutrition and physical activity and provide preliminary data that will help us design a large-scale dissemination study. Finally, we

anticipate that outcomes from aim 1 will help gain a better understanding of training needs and preferences in the OST setting, more generally, which will be helpful for planning future childhood prevention interventions.

***Potential problems and alternative strategies.*** We recognize that recruitment and retention could be an obstacle for aim 1, given that sites must agree to randomization. To address this concern, in 2014 we began working with YMCA leaders to develop OSNAP outreach strategies and plan to offer the intervention to control sites after establishing effectiveness. Plus, YMCA leadership has identified a gap that OSNAP could fill: while 90% of YMCAs nationwide have committed to adopting healthy nutrition and physical activity practices, only 31% report full implementation. Acknowledging the technical challenges that may arise online, we piloted this model and included time for Mr. Otis, who has provided web expertise in the OSNAP online development.

**2. Use mixed methods to identify actionable factors within the implementation context that influence the effectiveness of the OSNAP intervention delivered by two learning collaborative training models.**

***Introduction.*** Key to implementation and dissemination science is investigating what interventions work for whom and in what settings. The *objective of this aim* is to understand the influence of context on the effective implementation of the two learning collaborative training models. To attain this objective, we will test the working hypothesis that OST programs with a more supportive implementation context will more effectively implement the intervention than programs with a less supportive context. Quantitative survey data will help to identify the specific aspects of the intervention (e.g. complexity, design quality and packaging), outer setting (e.g. external policies), inner setting (e.g. resources and norms in the organization), and individual characteristics (e.g. experience, knowledge and skills) that impact effective implementation and subsequent qualitative interview data will help *explain* how these factors influence each training model in greater depth. When aim #2 has been completed, it is our expectation that we will be able to pinpoint the aspects of the OST context that are most influential on successful implementation of each OSNAP training model and use the voices of OST staff to describe how and why these real world factors matter. Such a finding would allow practitioners to choose the training model that suits the *context* of their OST setting and help our research team develop a comprehensive dissemination plan that can be tailored to diverse OST settings and personnel.

***Justification and Feasibility.***

***Review of Relevant Literature.*** In 2010, the Institute of Medicine (IOM) developed the L.E.A.D. framework to bridge the evidence gap in obesity prevention. (2) This framework encourages policy makers, researchers, and public health practitioners to focus on the population prevention of obesity with a systems approach, and to narrow the divide between what has been published in the scientific literature and what is practiced in community settings. (2) Our proposal aims to address this priority by identifying actionable contextual factors in real world OST sites that impact practice change in a nutrition and physical activity intervention using the Consolidated Framework for Implementation Research (CFIR). (55) While one clinical obesity management study has successfully employed CFIR to understand successful implementation (56) and two studies have investigated implementation processes and contextual influences of health interventions in OST settings, (57-59) to our knowledge no OST-based or childhood obesity prevention study has used CFIR. This review of the relevant literature demonstrates that there are strong frameworks for addressing our second aim, but limited public health research on the unique contextual influences in the OST setting. The proposed study responds to the IOM call to close the evidence gap with a mixed methods investigation of how the outer setting, inner setting, and individual characteristics impact effective implementation of two OST training models. (19)

***Preliminary studies.*** Below is a description of the preliminary studies that demonstrate our research team's capacity to achieve our objectives for aim #2. The investigation of the barriers and facilitators that OST staff face as they implement nutrition and physical activity changes has been core to our work with the YMCA nationally as well as locally in our OSNAP trial. In the 2007-2008 YMCA-Harvard Food and Fitness Project, Dr. Lee conducted interviews that indicated management structure, formal supports for staff, staff attitudes and buy in, relationships with the school and community, sufficient budget, and adequate space were mechanisms that impacted implementation. Given these factors identified in the YMCA interviews, Dr. Lee developed a pre-post survey for OSNAP to quantify the extent to which site directors experienced each factors hypothesized to impact effective implementation of nutrition and physical activity changes in out-of-school time. Following the Framework for Effective Implementation (60), we also collected objective data on the community context (e.g. neighborhood race/ethnicity and poverty), provider characteristics (e.g. site director years of experience and education level, staff turnover level), and organizational characteristics (e.g. presence of a kitchen or gym, site enrollment). In a study of the impact of these implementation factors on children's water consumption in the

OSNAP trial, we found that there were stronger effects for sites with on-site kitchens, low child-to-staff ratios , experienced site directors, and improved support from schools during the intervention period ($p<0.001$ for all factors). (17) We also found that the OSNAP intervention effect on children's consumption of procured foods and beverages differed according to foodservice operation. For instance, children at intervention sites with on-site kitchens had greater increases in fruit and vegetable consumption (0.31 servings/snack, 95% CI 0.20-0.42) than controls—a finding that was not detected in the main effects. Also, there was not an intervention effect among children who attended sites with satellite kitchens that get their snacks delivered from an outside vendor. (16) We are currently employing an explanatory sequential mixed methods design that uses qualitative interviews with OSNAP site directors to explain the quantitative survey data in greater depth. For instance, one director explained the challenges that arose with snack she received from the satellite kitchen, "Even after we got the menu, it still fell short…They never stopped serving juice. So we were stuck serving it… Things like that was such a hurdle. And we feel like we were never able to overcome it because it was out of our control." These preliminary data are important in establishing the feasibility of our second aim because they exemplify our team's capacity to conduct qualitative and quantitative research to investigate the impact of contextual factors on nutrition and physical activity intervention implementation and effectiveness.

***Research Design.*** We will use an **explanatory sequential mixed methods design** to assess the influence of the implementation context on the effective implementation of OSNAP. (34) CFIR serves as the underlying framework for Aim 2, using adaptations of validated measures and an interview guide aligned with the domains of the intervention characteristics, inner setting, outer setting, and individual characteristics. (35, 36, 56) (see Appendices) In spring 2017, simultaneous with Aim 1 follow-up data collection, we will collect **quantitative survey data** from all OST directors who participate in the OSNAP intervention**.** To quantitatively investigate the influence of the four CFIR domains on OSNAP implementation, we will add an aggregate score for each CFIR domain and an interaction effect to each of the main effects models from Aim 1. The effect estimate and p value for the interaction term will indicate whether that CFIR domain altered the intervention main effect. In fall 2017, we will conduct **qualitative one-on-one interviews** with trainers and OST directors to understand the influence of implementation context on OSNAP implementation in greater depth. We will take a stratified purposive sample at least 12 OST directors for interviews using Aim 1 OSNAP-OPAT practice changes to strategically choose information-rich cases (3 high implementation and 3 low implementation sites from each of the 2 training models) and continuing until saturation is reached. (34, 61) One hour semi-structured interviews will be audio recorded and transcribed. A cross-case analysis will begin deductively according to CFIR, then inductively code additional patterns and themes. Rigor will be ensured with analysis triangulation; all interviews will be coded by the PI and a second researcher to ensure reliability and multiple perspectives. (56, 61) Survey and interview data will be integrated after separate analyses, looking for concordant and discordant results. (34)

***Expected outcomes.*** Our team anticipates several significant outcomes from Aim 2 that will help to advance the field of implementation and dissemination science. First, following CFIR, we expect to identify actionable aspects of the OST implementation context that influence the uptake of OSNAP. These factors can be incorporated into the design of future training models and be used for tailoring, as results will help identify the best training model for a particular setting or practitioner. We believe our findings on the influence of contextual factors will be transferable to training on other health topics in the OST setting. This preliminary data will help set the foundation for a large-scale dissemination project by pinpointing any areas for refining our training models before further scaling up. Ultimately, we expect that this mixed methods approach will lead to the successful dissemination of the OSNAP intervention for maximum population health impact.

***Potential problems and alternative strategies.*** Our team recognizes that there are a limited number of factors from CFIR that we can assess in the quantitative strand of Aim 2. A final sample of 30 sites means that we have limited power to detect significant interaction terms that indicate the contextual influences on the training model effectiveness. For this reason, we are using a recently validated measure that collapses numerous contextual factors into one aggregate score for each of the four CFIR domains. (35,36) Furthermore, the qualitative component of our study will help to fill the gaps in our quantitative analysis by exploring in more depth the specific contextual factors that OST staff perceive as impacting effecting implementation.

**Future directions.** This research will serve as bridge between the OSNAP group-randomized trial and broad-scale dissemination. After assessing the impact of two training models on OST practice and implementation outcomes and investigating the influence of contextual factors, we will be able to identify how to scale up the OSNAP intervention. In the next step of our research continuum, we envision a large study that can test the training's impact on dissemination. This research will be a foundational stepping stone for our long-term goal of studying implementation and dissemination of evidence-based prevention interventions in community settings

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