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).

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424 R&R and PHS-398 Specific

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SF 424 R&R Face Page

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Grant Number: 1 R37 CA252113-01A1

Title: Testing an Adaptive Implementation Strategy to Optimize Delivery of Obesity Prevention Practices in Early Care and Education Settings

FOA: PAR19-274

FOA Title: Dissemination and Implementation Research in Health (R01 Clinical Trial Optional)

Organization: UNIV OF ARKANSAS FOR MED SCIS

Department: Family and Prevention Medicine

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Organization: University of Arkansas for Medical Sciences

Role Category: PD/PI

Project Summary

Consuming a healthy diet and maintaining a healthy weight provide significant protection against cancer and cancer-related mortality. Early interventions are needed to decrease the risk of developing cancer later in life. **Early care and education (ECE) is a promising setting for cancer prevention.**

"Together, We Inspire Smart Eating" (WISE) is an intervention that improves children's diets in ECE. WISE includes 4 key evidence-based practices (EBPs): (1) hands-on exposures to fruits and vegetables, (2) role modeling by educators, (3) positive feeding practices, and (4) a mascot associated with fruits and vegetables. Standard implementation approaches to WISE result in suboptimal implementation of WISE EBPs. Additional implementation strategies are needed to increase adoption and fidelity to EBPs.

To date, most studies have employed an "all-or-nothing" approach, comparing multifaceted strategies to control groups without implementation support. Thus, there is an urgent need for optimized strategies that tailor implementation support intensity to the unique challenges and limited resources of the ECE context. The overall objectives of this application are to determine the effectiveness and cost-effectiveness of an adaptive implementation approach to improve adoption of the EBPs of WISE while also examining implementation mechanisms. Our central hypothesis is that the addition of high-intensity strategies at sites that do not respond to low-intensity strategies will improve implementation and health outcomes.

Specific Aim 1. Determine the effectiveness of an adaptive implementation strategy that tailors the intensity of implementation support versus a low-intensity strategy. Using an enhanced non-responder trial, we will compare the effect of continuing low-intensity strategies vs. augmenting with high-intensity strategies. We hypothesize that sites receiving high-intensity strategies will outperform sites continuing the low-intensity strategies on the primary outcome of intervention fidelity and on secondary child health outcomes.

Specific Aim 2. Examine moderators and mediators of implementation outcomes in a mixed-methods design. We will test organizational readiness and teacher experience as moderators of response to the implementation strategies. We will test educators' perceptions of barriers, local implementation climate, and implementation leadership as mediators of the effect of the strategies on implementation outcomes. Qualitative data will explore other potential moderators and mediators not measured quantitatively.

Specific Aim 3. Assess the incremental cost-effectiveness of the adaptive implementation strategy. In this aim, we will estimate the cost per unit of fidelity associated with the adaptive implementation strategy. Results will also determine the incremental cost-effectiveness of applying the adaptive strategy compared to continuing low-intensity strategies for improving BMI and other child health outcomes.

Project Narrative

Arkansas (AR) and Louisiana (LA), the target locations for the current study, are among the states with the highest cancer and obesity rates in the US. Effective prevention and intervention programs are needed to reduce the number of children who develop unhealthy dietary habits and become adults with obesity, two key risk factors for the development of cancer. This proposal will test an adaptive implementation strategy to optimize the adoption of evidence- based practices for nutrition promotion and obesity prevention in early care and education settings.

Specific Aims

In the US, 4 out of 10 children are overweight or obese by age 5,[1] and few children between 2 and 5 years old meet dietary guidelines.[2-4] Consuming a healthy diet (e.g., fiber, antioxidant-rich foods)[5-7] and maintaining a healthy weight[7-9] protect against cancer and cancer-related mortality.[10,11] Arkansas and Louisiana are among the states with the highest obesity rates, lowest quality diets, and highest cancer rates in the US.[12] Given that early life patterns track into adulthood,[13,14] early interventions are needed to decrease cancer risk later in life. Importantly, studies in early care and education (ECE, i.e., childcare) found that 80% of dietary programs and 70% of programs focusing on health behaviors demonstrated positive effects.[15,16] **Thus, ECE is a promising cancer prevention setting. However, intervention implementation in ECE is a challenge.**[17,18]

"Together, We Inspire Smart Eating" (WISE) is an intervention that improves children's diets in ECE.[19,20] WISE includes 4 key evidence-based practices (EBPs): (1) hands-on exposures to fruits and vegetables, (2) role modeling by educators, (3) positive feeding practices to support children's self-regulation, and (4) a mascot associated with fruits and vegetables. Prior work by the study team documented that standard implementation approaches to WISE (i.e., training and reminders only) result in suboptimal implementation of WISE EBPs.[21] Additional implementation strategies are needed to increase adoption and fidelity to EBPs.

To date, few studies have compared implementation strategies to improve EBP uptake in ECE. Available studies have had a strong emphasis on policy, with results supporting the positive effect of multifaceted strategies.[22-26] However, these studies often used an "all-or-nothing" approach, comparing costly multifaceted strategies to control groups with no implementation support. Knowledge is limited on the intensity of implementation strategies that are needed to yield success; some organizations may need more intense strategies than others. Thus, there is a critical need for optimized implementation strategies that tailor intensity (high vs. low) to the unique challenges and limited resources of ECE. Further, understanding how strategies work and for whom (i.e., implementation mechanisms) will advance implementation efforts in ECE.

Our foundational work (K01-DK110141) showed that a high-intensity implementation strategy package outperformed a standard implementation for WISE. However, it is likely not possible or necessary to provide a high-intensity strategy to all sites in wider dissemination. Our proposed project will determine the optimal implementation intensity needed to improve the uptake of WISE EBPs in ECE. The overall objectives of this project are to determine the effectiveness and cost-effectiveness of an adaptive implementation approach to improve adoption of the WISE EBPs while also examining moderators and mediators of response to the strategies. Our central hypothesis is that the addition of high-intensity strategies at sites that do not respond to low-intensity strategies will improve implementation and health outcomes compared to the continuation of low-intensity strategies. **Our long-term goal is to increase EBP implementation in the ECE setting to improve health outcomes for children.** Thus, we propose the following specific aims:

Specific Aim 1. Determine the effectiveness of an adaptive implementation strategy that tailors the intensity of implementation support versus a low-intensity strategy. Using an enhanced non-responder trial, we will compare the effect of continuing low-intensity strategies vs. augmenting with high-intensity strategies to implement WISE. Low-intensity includes task-focused facilitation aimed at leaders; high intensity includes holistic, individualized facilitation aimed at educators. We will randomize non-responder sites (N =64) to continue with the low-intensity strategies or to add high-intensity strategies. We hypothesize that, on average, sites receiving high-intensity strategies will outperform sites continuing the low-intensity strategies on the primary outcome of intervention fidelity and on secondary implementation and child health outcomes.

Specific Aim 2. Examine moderators and mediators of implementation outcomes in a mixed-methods design. For moderation, we hypothesize that sites with weaker organizational readiness[27] and less experienced educators[28,29] will require high intensity strategies to reach fidelity. For mediation, we expect educators' perceptions of barriers,[21] implementation climate,[30] and implementation leadership[31] will mediate the effect of the strategies on implementation outcomes. Using an explanatory, sequential design, we will collect qualitative data at purposively selected sites (N =20) to identify emergent moderators and mediators.

Specific Aim 3. Assess the incremental cost-effectiveness of the adaptive implementation strategy. In this aim, we will estimate the cost per unit of fidelity associated with the adaptive implementation strategy. The fidelity change will be estimated based on a meaningful difference in our published fidelity measure.[32] Results will also determine the incremental cost-effectiveness of applying the adaptive strategy compared to continuing low-intensity strategies for improving child health outcomes.

IMPACT. The expected outcomes are refined knowledge on the outcomes, mechanisms, and costs associated with an adaptive approach to EBP implementation in ECE toward the goal of obesity prevention.

Significance

Importance of the Problem. By the late 1960s, researchers established that most cancers were related to environmental factors.[33] Fewer than 10 years later, studies showed that diet was just as much a cause of cancer as smoking.[34] Further, excess weight is linked with higher risk of 13 cancers,[9] and the US has the highest rate of cancer attributable to body mass index (BMI).[35] Over 600,000 individuals die, and $80.2 billion are spent each year as a result of cancer in the US.[36] The National Cancer Institute recommends healthy eating and weight management for cancer prevention.[37] However, Arkansas (AR) and Louisiana (LA) are among the states in the US with the highest obesity rates, lowest quality diets, and highest cancer rates.[12] Given the limited economic resources of these states, community systems need obesity prevention efforts that optimize resources through innovative, tailored implementation. Disparate disease burden and high healthcare costs will persist without effective implementation of evidence-based interventions.

Dietary habits and weight trajectories in early life predict later health outcomes;[13,14] thus, obesity prevention efforts must target young children. Specifically, children are 5 times more likely to remain overweight or obese in adulthood if they are overweight in preschool.[38] On average, 60% of US children under age 5 (15 million children) have at least 1 non-parental childcare arrangement per week.[39] Children spend 36 hours a week in ECE settings, on average.[40] Thus, the early care and education (ECE) environment is prime for reaching young children for obesity prevention. Despite the potential for ECE to promote healthy habits, a gap exists between current practices and evidence-based practices (EBPs).[41] This gap indicates a need to "overcome barriers to the adoption, adaptation, integration, and scale-up (PA-19-274)" of research evidence in ECE. **Our long-term goal is to increase EBP implementation in ECE to improve child diet and health outcomes.**

WISE: An Evidence-Based Intervention for ECE. Consistent with World Cancer Research Fund (WCRF) recommendations,[42] Together, We Inspire Smart Eating (WISE) aims to increase children's intake of carotenoid-rich fruits and vegetables (FV). WISE was co-developed with end users to meet the curricular and budgetary needs of the ECE context[43,44] and is included in the US Department of Agriculture SNAP-Ed toolkit.[45] Research supports each WISE EBP: (1) multiple hands-on exposures to FV support food acceptance;[46-52] (2) role modeling by educators allows children to observe a trusted adult eating FV;[53-55] (3) positive feeding practices support children's self-regulation;[55-57] and (4) mascot use associates a familiar character with FV.[58-63] Each EBP aligns with the Academy of Nutrition and Dietetics' "Benchmarks for Nutrition in Childcare."[64] Evidence also supports WISE as a whole.[19,20] Compared to usual education, WISE increased FV intake[19] (8% increase in healthy carotenoid levels; 4% decrease in unhealthy range).[20] Also consistent with WCRF guidance,[42] parents reported significantly decreased fast food and sugar-sweetened beverages intake after a year of WISE.[19,65] Thus, WISE has a positive impact in areas related to adult cancer risk.

WISE and ECE Implementation. Standard approaches to WISE implementation (training and reminders only) have resulted in challenges and suboptimal fidelity to EBPs.[66] Little research exists to guide solutions. For example, although studies have demonstrated that implementation strategies can promote policy implementation (e.g., menu offerings) and improve the environment (e.g., access to water),[67] few studies have assisted educators to implement EBPs in ECE.[68] Further, no available studies report on implementation mechanisms in ECE[68,69] (how *and* why strategies work *for whom*) or on cost-effectiveness of implementation strategies in ECE. Thus, practitioners lack data to drive decisions on EBP implementation in ECE.

Theoretical Foundation. The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework posits that components of successful implementation include characteristics of the innovation (the EBPs), recipients, context, and facilitation (i.e., implementation support).[70] Successful implementation takes place when facilitation promotes the acceptance and use of an innovation based on the recipients' and context's needs. Facilitation exists along a continuum.[71] On one end, task-focused support provides technical and practical help. On the other end, holistic facilitation provides enabling support to cultivate shared meaning, connected networks, and personal development.[71] **A central tenant of i-PARIHS is that successful implementation requires different levels and kinds of facilitation depending on characteristics of the innovation, the context, and recipients.** The i-PARIHS framework guides our proposal in several ways. Our formative work (K01-DK110141) identified determinants of WISE EBP implementation by applying i-PARIHS. These determinants guided engagement with stakeholders to select and tailor the proposed implementation strategies. Stakeholders prioritized *facilitation as a key strategy* to improve WISE EBP implementation, and we will tailor facilitation to reflect recipient and contextual needs. While i-PARIHS is ideal to inform implementation strategy tailoring, research has not tested it in this way (our Aim 1). Further, i-PARIHS has received limited tests of underlying mechanisms (our Aim 2),[72-74]

with most studies in health care.[75,76]

Need for Adaptive Implementation Strategy. Consistent with i-PARIHS, adaptive implementation strategies reflect that a one-size-fits-all approach may not serve all settings well.[77] Not all sites may need all strategies; giving sites more than they need is expensive and wasteful. An adaptive implementation strategy provides decision points and tailoring variables to optimize resources. **Table 1** presents the design features of an adaptive implementation strategy. In sum, an adaptive implementation strategy provides a "replicable guide" for *who* gets *what* implementation support and *when*.[78]

Table 1. Adaptive Implementation Strategies Decision Rules

Design Features	Definition
Crucial decision points	Which strategies to begin the study (i.e., low intensity)
	How and when response is measured
	What strategies are given to non-responders (i.e., high intensity)
Tailoring variables	Measurement to identify non-responders and inform strategy intensity

Rigor of Prior Research & Preliminary Data. The USDA-funded WISE study, a small-scale implementation trial (K01-DK110141), and a COBRE Research Project provide the preliminary data.

The USDA funded the original development and evaluation of WISE. This 5-year study (2011–2016) took place in 2 phases. First, our team gathered stakeholder input through focus groups and interviews on ways to implement targeted EBPs; we used this input to structure the WISE curriculum and training. We completed pilot tests of each unit in 3 classrooms at 2 sites, collected feedback from educators, and made revisions to increase feasibility and acceptability. Second, we tested the WISE curriculum in 22 Head Start classrooms at 5 sites and compared child dietary outcomes to a control group of children not receiving WISE. Besides documenting child outcomes as outlined prior, this study allowed our team to develop and refine implementation fidelity measures,[79,80] assess EBP fidelity with a standard implementation approach (training and reminders only), and document educator reactions to the intervention.[44] This study demonstrated:

1. ECE educators accept WISE. ECE educators implemented the WISE intervention versus outside agents. Educators reported enjoying WISE (94%) and recommending the curriculum to others (88%).[44]
2. Standard implementation approaches produce highly variable implementation. Classroom fidelity rates ranged between 16% and 48%,[79] with fidelity to both hands-on exposure and positive feeding practices dropping by over 10% across the school year.

In the K01 study (2016–2019), we collected formative evaluation data to understand barriers and facilitators to WISE EBP uptake. Then, we engaged local stakeholders[81] (educators, directors, cooks, and parents) to identify the most crucial implementation determinants. Researchers mapped key determinants to potential implementation strategies.[82,83] Next, stakeholders rated potential strategies on importance and feasibility. This process resulted in a stakeholder-driven, multifaceted implementation strategy package including 7 discrete strategies: (1) formal leadership commitments, (2) local site champions, (3) an implementation blueprint, (4) reminders for educators, (5) facilitation individualized to educators, as well as (6) tailored educational materials and (7) incentives. To examine the strategies' potential, we deployed a *small-scale* Hybrid III cluster-randomized trial that compared the intensive package of strategies to a standard implementation condition receiving only training and monthly reminders (N =9 sites, 38 classrooms, 75 educators, 621 children). All sites were Head Start; the trial was one school year. The K01 showed:

3. WISE, like other ECE-based interventions,[84-86] has faced implementation challenges. Informed by the i-PARIHS framework, a developmental evaluation identified over 50 unique implementation barriers and facilitators to WISE EBP implementation.[21] Implementation barriers prioritized by stakeholders included leadership support; educators' beliefs, knowledge, and skills; and the climate supportiveness of WISE. These priorities drove selection of strategies for subsequent testing.
4. The stakeholder-selected, intensive implementation strategy package outperformed a standard implementation condition for improving WISE implementation outcomes. The intensive strategy package resulted in a meaningful, significant difference in fidelity for 3 of the 4 WISE EBPs (role modeling P =.03, hands-on P =.02, mascot P <.001, all effect sizes >.80). Educators receiving the intensive strategy package rated WISE as more appropriate (P =.03) and feasible (P =.05).[87]
5. EBP fidelity was associated with child outcomes. Fidelity to mascot use was related to change in child BMI (r = -.15, P =.03), and supportive feeding practices were related to child carotenoid levels (r =.46, P <.001).

6. The K01 intensive strategy package improved implementation mediators suggested by i-PARIHS. Educators receiving the implementation strategy package experienced (1) fewer perceived barriers to implementation (*P* =.008), (2) greater leadership support[31] for WISE implementation (*P* =.01), and (3) increased organizational readiness for implementing change[88] (*P* =.04).
7. The intensive K01 strategy package cost $274 per classroom across 9 centrally located sites. This cost reflected travel time (23% of cost), facilitator salaries and benefits (39%), incentives and resources (21%), and miscellaneous costs, including training materials (17%). This cost was up to 80% lower than prior estimates for annual facilitation costs in health care[76] and 90% lower than prior estimates in schools.[89]

These data suggest the intensive package of stakeholder-selected strategies was effective for improving WISE EBP implementation. Yet, we do not know if all sites require all strategies to succeed. Scaling to all sites may be too resource- and time-intensive for wide dissemination.[90] **The strategies tested in the K01 need to be separated and sequenced to inform future real-world implementation that considers the limited resources of ECE.** Further, the K01 documented the intensive strategy costs in ECE, but we do not know the cost-effectiveness of a strategic, adaptive approach that applies high-intensity strategies only when needed.

Through an NIH-funded COBRE Research Project (2020), we gathered stakeholder input to design our adaptive implementation strategy, a critical step in the absence of prior adaptive implementation strategy testing in ECE. COBRE data helped tease apart the K01 intensive package into "low intensity" and "high intensity" packages. Low intensity includes the "standard" implementation from the USDA study (i.e., teacher training) plus additions that stakeholders believe all sites will need. High intensity support includes tailored support for sites that do not respond to low-intensity. Stakeholders were educators who had received the intensive strategy package and shared input through semi-structured interviews (*N* =10).

8. Stakeholders provided feedback to delineate the low and high intensity packages. This resulted in a reduced number of strategies (i.e., dropping incentives) and adjusted timing (e.g., train champions earlier).
9. Stakeholders helped define the tailoring variable and decision points for the adaptive implementation strategy. Consistently, stakeholders recommended the tailoring variable rely on classroom observations early in the school year (Oct stated most). Stakeholders emphasized that all sites need some facilitation; struggling sites need more. Thus, in our adaptive implementation strategy, low-intensity facilitation will include task-focused monthly contacts between WISE facilitators, leadership, and the champion (without direct educator support). High-intensity facilitation will be individualized to educators and holistic.
10. Stakeholder perspectives guided the definition of non-response. Generally, stakeholders said that sites with a minority of classrooms implementing successfully would need high intensity added. Thus, we set our threshold to define non-response as 60% of classrooms failing to meet fidelity for most (3 of 4) EBPs.

The resulting adaptive implementation strategy package is specified as recommended by Proctor et al.[91] (**Table 2**). Low intensity strategies include those that all sites receive at the beginning. High intensity strategies are added at non-responders sites. Specifically, the facilitator receives data from the fidelity observation to coach and guide the educators in behaviors needed to support non-responders in achieving fidelity to EBPs.

Table 2: Specification of Adaptive Implementation Strategy

		Strategy	Actor(s)	Action	Temporality	Dose	Justification
Non-responders get addition of HIGH INTENSITY	Begin with LOW INTENSITY	Obtain formal commitments	WISE facilitators & directors	Sign commitment after facilitators & directors discuss	Before educator training	One-time meeting	Address leadership buy-in
		Identify & prepare local champions[92,93]	Appointed champion at each site	Provide 2-hour training on navigating WISE	Within 2 months of training	1 training: contacts monthly & on request	Address capacity for change & climate supportiveness
		Develop implementation blueprint [94]	WISE staff with directors & champions	Provide target milestones & testimonials	With director before training	As desired	Give leaders tools to support change integration
		Remind educators[95,96]	Classroom cutting board	Provide visual reminder of EBPs	At WISE lessons	As desired	Provide timely reminders
		Task- focused implementation facilitation[75,76,82,97]	WISE facilitators, directors & champions	Provide support to directors & champions	Beginning 2 weeks after training	Monthly	Provide practical & technical help to site leader & champion; task & goal focus[71]
		Holistic individualized facilitation [75,76,82,97]	WISE facilitators & educators	Provide in-person visits to directors, champions & educators	Beginning 2 weeks after training	Twice monthly; more upon request	Create and connect networks; holistic/ enabling focus on educators[71,98]
		Distribute tailored educational materials [70-72,75,76]	WISE facilitators, champions, & educators	Provide educators with tailored EBP education	Each quarter	Varies by educator (up to 8)	Address barriers of beliefs, knowledge and skills for EBPs

Tailoring variable = classroom WISE fidelity observation in Oct
Non-responders = sites with fewer than 60% of classrooms meeting fidelity for 3 of the 4 WISE EBPs

Significance Summary and Expected Impact. Our study is significant for several reasons. First, given the link between diet quality, excess weight, and cancer,[101] the work is consistent with the NCI focus to accelerate cancer prevention.[75,102] It also responds to the NIH Obesity Research Strategic Plan[103] to evaluate prevention strategies in real-world settings, as well as to the NIH 2020–2030 Strategic Plan for Nutrition Research[104] objective to "leverage behavioral and implementation science to initiate and sustain healthy eating behaviors." Second, ECE is a key real-world context for nutrition promotion and obesity intervention,[64,105,106] but implementation gaps persist in this setting. Thus, this research has substantial potential to inform pragmatic guidance on the strategy intensity needed to implement and scale health-related EBPs in ECE. This is critical given that ECE, particularly programs in our study, serves children of minority and lower-SES status, populations at higher child obesity risk.[107] Third, our study represents a significant contribution to "testing theories, models, and frameworks for D&I processes (PA-19-274)." Specifically, our examination of i-PARIHS–suggested moderators and mediators will test the "encapsulated theory" implied by this framework.[70] Finally, our research models implementation outcomes, health outcomes, and implementation costs for WISE in ECE. Measuring this combination is rare but necessary to optimize feasible implementation approaches.[108]

Innovation

The status quo in testing implementation strategies for nutrition promotion in ECE is to compare implementation strategies to usual care (no implementation strategies).[68] Such comparisons provide little insight into the strategy intensity needed to improve implementation while optimizing resources. Thus, gaps remain in EBP implementation for obesity prevention in ECE.[18,69,109] The proposed research is innovative because it represents a substantive departure from the status quo by testing an adaptive implementation approach. This departure is guided by a recently published "research agenda"[110] on implementation strategies, including priorities to enhance methods for tailoring strategies and accelerate effectiveness research on multifaceted and tailored strategies. Specifically, **we will contribute to a paradigm shift *from* one-size-fits-all implementation strategies *to* strategically sequenced implementation strategy packages.** This approach has the potential to optimize the minimum resources needed to achieve the desired outcomes. We expect this innovative approach to identify which sites need what level of support for implementation success. This will inform the development of a scalable adaptive implementation strategy guide with real-world relevance. Our aims will simultaneously address expert recommendations[110] to increase economic evaluations of implementation strategies and specify and test implementation mechanisms, producing novel findings for implementation science as well as early education. Thus, **our research also represents a shift away from *if* strategies produce improved implementation outcomes to *how* and *at what cost*.** Further, our study will add to the only 7 available mixed-methods studies on implementation mechanisms[69] and be among the first to parse and compare elements of facilitation approaches to understand what is needed in practice for whom.

Approach

Overall Strategy and Rationale

We will use an enhanced non-responder trial[77] design to determine the effectiveness (Aim 1) and incremental cost-effectiveness (Aim 3) of an adaptive implementation strategy for WISE, while examining moderators and mediators of the strategy effect (Aim 2). In this trial, we will randomize sites that do not respond to low-intensity strategies to either (a) continue receiving low-intensity strategies or (b) receive high-intensity strategies (See Figure 1). **This design will determine the effect of an adaptive implementation strategy that adds high intensity versus one that continues with low intensity among non-responder sites**. This trial

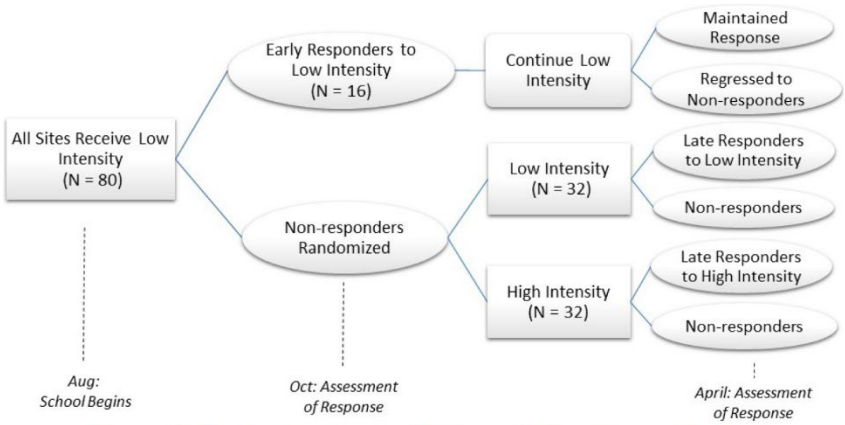

Figure 1. Cluster-Randomized Enhanced Non-Responder Trial

design has two key advantages.[77] First, data collection across the entire study informs identification of moderators to inform improvements to the adaptive implementation strategy guide (i.e., who needs what and when). Second, secondary analyses can consider the time course of response (i.e., whether some sites need more time with low intensity, if early responders maintain response).

Implementation Sites. Sites will be from 4 geographic regions: Central AR, AR River Valley, North Central LA, and Southeast LA. A site is one ECE location; a site may have multiple classrooms with up to 20 children per classroom. A director provides leadership at each site; educators implement WISE in their classrooms.

Site Inclusion/Exclusion Criteria: Sites within a 100-mile radius of staff offices; participating in the Child and Adult Care Food Program (CACFP) and the state's quality rating system; serving 15+ children ages 3 to 5 years; agreeing to participate in data collection; and not currently using WISE can be included. We will exclude sites unwilling to adopt WISE for all classrooms. Focusing on CACFP will maximize equitable reach, generalizability, and study impact. A focus on CACFP builds upon our prior work that documented gaps in adoption and significant barriers to EBP use in CACFP-funded sites (i.e., all USDA/K01 sites were CACFP).[21] While CACFP provides sound meal pattern guidance, this guidance has neither reliably improved educators' knowledge or practice[111] nor children's healthy food intake.[111] Further, studies demonstrate implementation of the most recent CACFP standards at fewer than 23% of CACFP sites in some states.[112] Most importantly, CACFP is a federal system that serves 3 million children per year,[113] "targeting benefits to those children most in need."[114] CACFP provides snack funds, removing the barrier of food costs for WISE implementation.

Study Recruitment Procedures. We will recruit 80 sites (40 in AR, 40 in LA). We expect recruitment to be successful because of strong statewide partnerships and guidelines encouraging ECE to provide nutrition education (See **Letters of Support, LOS**). We have already identified 300+ sites that meet our criteria and completed recruitment for Cohort 1. We will recruit sites diverse in Quality Rating and Improvement Systems scores,[115] and we will model ratings in our analyses. We will recruit sites in 3 cohorts, 25–28 sites per year in 3 school years (across Y1-Y4). Cohorts will increase feasibility (See **Study Timeline** attachment). Cohort size per state is comparable to that managed by the PI in the K01. We will pool data across years for analyses, and we will include cohort assignment as a control variable. A cohort-based design will allow us to limit the number of sites to 4 or less per facilitator per year—a number for which prior work indicates the greatest effect.[75]

Classroom Inclusion Criteria: All classrooms at a site will receive the same implementation strategies and participate in data collection. This reflects stakeholder input that sites would not participate unless all classrooms are treated equally. For analyses, we will include only classrooms that are non-responders. In this way, we avoid contaminating analyses with classrooms that respond to the low-intensity strategy against the site trend. Based on our ECE experience, we expect 3 non-responding classrooms per site, on average; we have powered accordingly. Thus, we plan to include 192 total classrooms at 64 sites in our primary analyses. The early responder sites and classrooms (16 sites, 48 classrooms) will be included in exploratory analyses.

Child Inclusion Criteria: We will select one classroom at random per site to participate in collection of child outcomes (N = 64 classrooms, 15 children per classroom = 960 children total). Parents will provide consent.

Randomization. The study will be cluster-randomized at the site level; we will randomize non-responder sites. Typically, researchers anticipate the number of non-responders based on theory, prior studies, and preliminary data. Diffusions of innovations suggests that up to 16% may be early adopters.[116] Prior adaptive studies in community settings have shown 20% - 56% early response.[117-119] In the small-scale K01, about 10% of classrooms were responders by the fall assessment (achieved fidelity to 3 of 4 EBPs). Considering these factors and that this study is larger and more diverse than the K01, we anticipate at least 20% of sites will be responders after 2 months, leaving 80% of sites as non-responders for randomization. Higher non-response rates would improve statistical power. The biostatistician will randomize non-responder sites in a 1:1 ratio to the low-intensity or high-intensity strategies consistent with procedures of minimization and balancing.[120,121] First, the biostatistician will assess all possible random assignments for the balance between groups on potential confounding factors (e.g., site size, number of non-responder classrooms, demographics). We will randomly select one assignment from the list of random assignments with acceptable levels of balance, which will balance sites on key factors while preserving advantages of randomly assigning sites.[120,121]

Relevance of Results to the Community. Community partnership is key to reduce cancer-related health disparities.[122,123] To this end, we will draw on Evidence-Based Quality Improvement (EBQI) methods, in which we are well-versed.[81,124,125] This process will develop researcher–stakeholder partnerships for joint decision making,[81,124-129] consistent with Community-Engaged Dissemination and Implementation principles.[130] Our EBQI panel will include educators, directors, and staff from ECE as well as state policy leaders who can inform

WISE scale-up. For example, at least 3 professional networks could use the adaptive approach we develop: CACFP sponsors, Childcare Resource and Referral (CCR&R) agents, and USDA Cooperative Extension agents (See **LOS**). The panel will meet 3 times per year and provide input into study recruitment, roll out of study protocol, interpretation of findings, and future planning. We will also disseminate our results back to participants and stakeholders through infographic-style summaries and presentations at community events.

Research Team Expertise. *Our team leverages the expertise of international leaders across multiple disciplines.* **Taren Swindle, PhD,** is an NI and ESI with significant expertise in mixed-methods research[21,131,132] and research in ECE (14+ years). She has established her expertise at the intersection of nutrition and implementation science[133-136] and has a collaborative history with all Co-Is. **Geoff Curran, PhD,** is an international leader in implementation science[137-140] with expertise in the proposed study methods (e.g., EBQI,[81,125] implementation costs[141]) who has served as a mentor for Dr. Swindle for 5 years. **Julie Rutledge, PhD,** brings expertise in child development, 17 years of experience with school-based interventions, and 7+ years of collaboration with Dr. Swindle.[32,80,142,143] **Leanne Whiteside-Mansell, EdD,** is a WISE co-inventor[144] with over 25 years of experience designing and evaluating interventions in ECE.[145-147] **Susan Johnson, PhD,** is an expert in child feeding research with over 25 years of experience.[148-151] **Jacob Painter, PhD,** brings 8 years of experience conducting cost-effectiveness analyses in clinical and D&I studies.[152-154] **James Selig, PhD,** is a biostatistician with experience in all proposed analyses.[32,132,155] Consultants in adaptive implementation designs and health equity will complement the team (See **LOS**). **Daniel Almirall, PhD,** is the leading expert in adaptive interventions in D&I studies[77,78,118,156] and will continue to advise on study design. **Tracey Barnett McElwee, PhD, LMSW,** brings 12+ years of experience in the application of health equity to qualitative research.[157-159] The Overall Structure of the Study Team attachment outlines project responsibilities.

Robust and Unbiased Results. We will compare the effect of 2 intensities of implementation strategies on implementation and health outcomes. Thus, our study is a clinical trial. Participants' race, ethnicity, and sex will reflect the educators' and families' demographics in the respective states (See Planned Enrollment). Over 96% of the US ECE workforce is female;[160] we will examine sex as a biological variable for educators when the appropriate sample size exists. We will examine differences by sex for child outcomes.

Specific Aim 1. Determine the effectiveness of an adaptive implementation strategy that tailors the intensity of implementation support versus a low-intensity strategy.

Rationale. Our work builds on community-based adaptive implementation strategy trials[117,156] to examine an adaptive implementation strategy in ECE. The objective of Aim 1 is to test an approach that would provide more precision in implementation support and increase scalability potential. We will test the hypothesis that for sites not responding to low-intensity strategies initially, the addition of high-intensity strategies will result in improved outcomes compared to sites that continue low-intensity strategies. Our approach uses an enhanced non-responder trial.[161] The rationale is that "all-or-nothing" approaches to implementation may not be cost-effective or feasible in the real world; rather, practitioners need an adaptive strategy to allocate appropriate resources for implementation without under or over investment. We expect this aim to produce data on the effectiveness of an adaptive implementation strategy for supporting EBP implementation in ECE.

Methods. Table 3 presents the Aim 1 data collection plan. Measures align with Proctor's Outcomes for Implementation Research taxonomy.[163] The school year calendar informs measurement timing. **The primary outcome is fidelity to the WISE EBPs at the classroom level.** We will use the WISE fidelity observational measure.[64] The measure includes 2 to 3 items per EBP on a 1 to 4 scale to receive an average, continuous fidelity score with 4 representing the highest fidelity. For each item, values are anchored to concrete, observable behaviors. Trained and field-reliable staff blinded to the study condition will collect fidelity data consistent with published protocols.[64]

Table 3. Aim 1 Measures & Data Collection Plan

Constructs	Measures	Frequency
Fidelity	WISE fidelity[64]	Oct, Jan, April of school year
Acceptability, feasibility, appropriateness of innovation *and* strategies	Weiner et al. pragmatic measures[87]	Aug, Jan, April of school year
Adoption	WISE delivery survey[66]	Monthly during implementation year
Sustainability	WISE delivery, WISE fidelity[64]	Fall of following school year
Child health outcomes	RRS,[130] BMI,[162] consumption[127]	Aug & April of school year

Secondary implementation outcomes are adoption as well as acceptability, feasibility, and appropriateness of WISE *and* the implementation strategies.[87] We will collect secondary outcomes through *self-report from*

educators on the schedule in **Table 3.** The WISE delivery survey[66] captures the number/content of lessons delivered and material dissemination to parents. In the next school year, we will assess EBP sustainment (i.e., delivery and fidelity 12-18 months after initial implementation).

To measure the effect on child health outcomes, we will use Resonance Raman Spectroscopy (RRS), which measures skin carotenoid levels as a biomarker for colorful FV intake[164] with an optical hand scan.[165,166] RRS reflects intake over the prior 4 weeks and is sensitive to individual differences and experimental changes.[167,168] Trained staff will assess BMI with a standardized protocol[162] and interpret the data with 2000 CDC growth charts.[169] Finally, we will observe children's target food intake with a standardized protocol used by our team in prior studies.[127-128] We will weigh food portions (to the nearest 0.1 g) before and after observation.

Implementation Processes. First, site leadership will meet with WISE facilitators to discuss the formal commitment and implementation blueprint. Next, all staff will receive WISE training. At training, educators will receive the "reminder cutting board," showing the 4 WISE EBPs for use during lessons. Next, sites will select a "champion" to be a liaison between the site and WISE facilitator. Champions receive standardized training to navigate WISE implementation before September.

Facilitation. In the low intensity group, WISE facilitators will provide monthly task-focused facilitation targeted to site directors and champions. Facilitation in the low-intensity group will monitor implementation, identify and solve problems related to contextual barriers, and assist with navigating structural changes needed for WISE. In the high intensity group, WISE facilitators will provide holistic, enabling facilitation tailored to the needs of the educators twice per month and more upon request. Facilitation in the high-intensity group will support educators in a one-on-one fashion, helping to set goals, fostering peer networking, developing shared vision among leaders and staff, and building meaningful relationships that support change efficacy. This will include the provision of tailored educational materials and coaching based on observed fidelity reports. Each study region will have 2 trained facilitators with experience in the ECE setting and/or WISE. Further, all facilitators will receive standard training and toolkits (e.g., sample scripts, testimonials, motivational interview examples). This is based on the Veterans Health Administration Implementation Facilitation Training,[171] which 2 study staff completed in 2019. This training has been adapted for WISE and delivery in a 4-hour session. After training, new facilitators will accompany experienced facilitators for 2 field visits to observe. The new facilitators will lead at least 2 visits with support and feedback from the experienced facilitator. Facilitators will take part in monthly reflective supervision calls led by the PI. All facilitators will log their activities (e.g., visits, calls, emails, champion contacts). The PI will compare the facilitator logs against the core implementation facilitation activities checklist for fidelity monitoring[172] and provide corrective guidance as needed.

Data Management and Analyses. We will manage data with REDCap,[173] a secure, web-based electronic data capture tool hosted at UAMS. We will use SPSS Statistics v25 (IBM) for Aim 1 analyses. Analysts will examine data for missing values, extreme scores, and variable distributions. We expect missing values on the primary outcome to be minimal because study staff will collect these data. If the missing values percentage exceeds 5%,[174] we will use a multiple imputation approach for analyses. **For our primary analysis,** we will use linear mixed-effects regression models[175] to test for group differences in fidelity outcomes at the school year end, while accounting for classroom nesting within site. Covariates will include state, site size, cohort, turnover rate, October fidelity, quality rating, and demographics. The statistical significance of the treatment group predictor (alpha =.05) will be used to determine significant differences in fidelity outcomes for the low- vs high-intensity groups. Additional analyses will include repeated outcomes from all time points to test for treatment group differences across time and time-by-treatment effects. We will repeat these analyses for secondary implementation outcomes. We will also examine child-level outcomes using linear mixed-effects regression models, which account for a child's nesting within classrooms and sites. Parallel to primary analyses, we will first test treatment group differences at the spring assessment and then examine treatment and time-by-treatment effects using all time points. For all analyses, a significant, positive effect of treatment group will support the effectiveness of applying high-intensity strategies at sites that do not respond to low-intensity strategies initially. An exploratory analysis is to describe the number of sites that were early responders and maintained response until the April assessment (versus regressing to non-responders over time).

Statistical Power. For power analysis, we used Optimal Design software[176] to accommodate the clustered design of classrooms nested in sites. Our estimated sample size is based on the primary fidelity outcome and is analogous to powering a 2-arm randomized controlled trial. We have powered our study to detect a practically meaningful 1-point difference on our fidelity scale: 1 point would differentiate an educator who

implements a practice only somewhat (e.g., score of 2) from an educator who implements a practice to a significant degree (e.g., score of 3). Based on standard deviations from the K01, a 1-point difference would yield Cohen's d effect sizes between .83 (Mascot) and 1.68 (Role Model). Assuming 64 non-responder sites (assigned 1:1) with an average of 3 non-responding classrooms per site (192 classrooms), the largest previously observed 0.20 Interclass Correlation Coefficient (ICC), and 2-sided α =.05, we will have 80% power to detect an effect size of d = 0.49 or larger. We do not anticipate site-level attrition, but even with ~20% attrition (N = 50 sites), we would have 80% power to detect an effect size of d =.56 or greater. Assuming one randomly chosen classroom per site, 15 children per classroom (N=64*15=960), a 0.10 ICC (largest observed child-level ICC in the K01), and 2-sided α =.05, we will have 80% power to detect an effect size of d =.29 or larger for child-level outcomes, which corresponds to an effect size of between small and medium.[177]

Expected Outcomes. Our analyses will provide data on the value of augmenting low-intensity strategies with high-intensity support. We expect data from this to serve practitioners in ECE (e.g., CACFP, CCR&R, and Extension), local agency directors, and state-level policy makers in allocating resources to implement EBPs. Thus, this study will provide crucial data to inform WISE scale-up and dissemination—applicable lessons for other interventions and contexts. Follow-up assessments will reveal how the implementation strategies affect WISE EBP sustainability in school years following the initial WISE launch. For example, we will be able to compare sustainability between sites that respond early to low-intensity strategies (by Oct assessment) and sites that respond late to low-intensity strategies (by school year end). Further, this aim will provide unique knowledge for the implementation science field about facilitation, allowing comparisons between the effect of a strategy bundle with narrowly focused facilitation and a more holistic, individualized facilitation.

Potential Problems & Alternative Strategies. First, sustainability assessment is best beyond 24 months. However, resources of the current study will provide preliminary data on sustainability at 12 to 18 months, a prerequisite to longer-term sustainability. Future studies will explore factors that contribute to longer-term sustainability. Second, staff turnover can be significant in ECE. At the low-intensity sites, facilitators would encourage local site champions to demonstrate a WISE lesson and follow up by providing resources and inviting questions; at the high-intensity sites, WISE facilitators would visit new educators' classrooms during a WISE lesson to answer questions and identify resource needs. We will include turnover as a covariate in analyses. *Other Trial Designs Considered:* Our trial design is akin to the popular Sequential Multiple Assignment Randomized Trial (SMART) design,[77] the key difference being a single randomization point for sites that do not respond to the initial implementation strategies. The school year calendar could not accommodate multiple randomization points. We also considered a 2-arm cluster randomized trial in which one group received the adaptive implementation strategy, and one group received the low intensity strategy. The enhanced non-responder trial is preferred because it allows for detailed refinement of the tailoring variable by identifying pre-randomization site characteristics that predict response. We will gain this in-depth understanding to inform future tailoring through Specific Aim 2.

Specific Aim 2. Examine moderators and mediators of implementation outcomes in a mixed-methods design.

Rationale. Tests of theory in implementation science are limited;[178] exploration of the moderators and mediators suggested by frameworks has only been proposed recently.[70] Our objective is to test (quantitatively) and investigate (qualitatively) moderators of response to low-intensity strategies as well as mediators that explain the mechanism by which implementation strategies influence implementation outcomes.[179] The rationale for Aim 2 is to understand *how, why* and *for whom* the effects of our adaptive implementation strategy are achieved (or not achieved) rather than simply *whether* the effects are achieved.[180] For moderation, we will test the hypotheses that sites with a weaker organizational culture and less experienced educators will require the high intensity strategies to reach fidelity. This is consistent with the i-PARIHS framework, which describes contextual and recipient characteristics as key influences on implementation. For mediation, we will test the hypotheses that the effect of facilitation is mediated by educators' perceptions of barriers, implementation climate, and implementation leadership (**Figure 2**). The i-PARIHS framework is ideal to inform the study of mediators given the specification of facilitation as the "active ingredient" of implementation.[71,181,182] Based on i-PARIHS, we expect that mechanism activation will be greater in sites receiving high-intensity support. This is because high-intensity support differs from low-intensity in 3 ways: (1) it targets a broader range of recipients, individualizing to educator needs; (2) it has a more holistic focus,[71] working to support organizational

learning capacity;[182] and (3) it happens more frequently. We will also identify additional candidate moderators and mediators through purposive interviews and site visits for each responder type. Specifically, we expect results to provide practice-relevant information on which sites need high-intensity strategies. Further, our mixed-methods design will provide complimentary data on the "how and why of strategy impacts."

Figure 2. Conceptual Model of Proposed Moderators & Mediators

Methods. We will use an explanatory, sequential mixed methods design (QUANT→qual) to provide a nuanced understanding of implementation mechanisms and contextual factors.[183,184] Quantitative analyses will test 2 moderators and 3 mediators specified a priori (See **Figure 2),** while qualitative methods will provide detail and elaborate on potential additional candidate moderators and mediators at a subset of sites of purposively selected sties based on response type.

Quantitative Procedures. During the baseline period (prior to Oct), educators at participating sites will complete assessments of potential moderators and mediators. Educators will also complete surveys mid-year and at the school year end to assess proposed mediators. We expect 2 educators per classroom to complete the survey, 6 per site on average. This follows the best practice of assessing moderators before randomization[185,186] and assessing mediators at a minimum of three points in time.[187,188] Further, our design includes key features to establish causal inference including temporality and experimental manipulation of dosages of facilitation.[189] Educator responses will reflect site experiences, and we will aggregate educator responses to the site level for analyses. The research team will collect these data in person with paper surveys or emailed survey links (reflecting technology access and use in ECE). We will capture data with REDCap for secure storage. All classroom staff (lead and assistants) will complete assessments.

Moderation. Organizational culture predicts care quality in health care[190,191] and moderates response to implementation strategies.[192] Further, research by our team and others has linked early educator background with personal nutrition and EBP use,[193-196] suggesting it as a prime target for moderation of response.

Moderation Measures. Moderation measures will include The Organizational Readiness to Change Assessment (ORCA),[27] which we adapted and tested in ECE in our prior work. For this study, we will focus on the context subscale, which is consistent with our focal moderator and based on i-PARIHS. The baseline survey will also capture educator background including years of experience and type/ frequency of prior nutrition and feeding training to create a composite educator experience variable.

Mediation. Lewis et al.[179] recommend a process for examining mediators in implementation research: (1) specify implementation strategies (See **Table 2**), (2) generate strategy–mechanism linkages, and (3) identify proximal and distal outcomes. For both the low- and high-intensity strategies, implementation facilitation provides the umbrella under which other implementation strategies are used. Thus, we will focus on mechanisms theorized to be activated by facilitation. First, we hypothesize that facilitation will decrease the perceived barriers to implementation (e.g., by helping to identify problems and solutions).[71] The presence of fewer perceived barriers has been associated with improved EBP use.[197] Second, we expect that facilitation will improve implementation climate (e.g., by developing shared meaning,[71] assisting with boundary navigation, and supporting role clarity[71,182]). Implementation climate has been associated with positive attitudes towards EBPs,[198] success in medication management implementation,[199] and improvements in evidence-based psychotherapy use.[200] Finally, we hypothesize that facilitation will improve implementation leadership and the knowledge and behaviors leaders leverage to support EBP implementation[31] (e.g., by navigating group interests, modeling empowerment, and building organizational structures[71,182]). Implementation leadership has been associated with positive attitudes toward EBPs,[198] success in medication management implementation and EBP use in acute care,[201] and implementation improvement in evidence-based psychotherapies and community mental health.[202] For steps (2) and (3), **Figure 2** presents our proposed model that links facilitation to the proposed mediators (proximal outcomes) and targeted implementation outcomes (distal outcomes).

Mediation Measures. Facilitation (e.g., dose, target) will be measured using the facilitation logs described in Aim 1; however, we will conceptualize facilitation dichotomously for analyses (high and low intensity). We will apply widely used and validated measures of proposed mechanisms, including the Implementation Climate Scale[30] and Implementation Leadership Scale,[31] recently adapted for educational settings;[203] the perceived barriers measure[21] is a checklist of challenges educators reported in our formative work and used in the K01.

Quantitative Data Analyses. Analyses will include 64 sites randomized (1:1) to the low- or high-intensity strategies. Moderator analyses will be conducted in SPSS using mixed effects logistics regression models with a treatment main effect (low- vs high-intensity), the moderator main effect (organizational readiness and educator experience), and the interaction between the two. The interaction term significance (alpha =.05) will be evaluated to test moderation. Models will account for the classroom nesting within sites and include controls for state, quality rating, and key demographics. For mediation analyses, we will test a multilevel, multiple mediator model in a Structural Equation Modeling (SEM) framework[204] to account for students clustering in classrooms and classrooms within sites using MPLUS software. Specifying a multiple mediator model is less biased than testing single mediators one at a time.[205] Using parametric bootstrapping (Monte Carlo)[206,207] significance tests in SEM are also less biased than sequential hypothesis testing approaches to mediation tests.[208] Using data at three time points, we will be able to model that Y (independent variable) precedes M (mediator) in time, and M precedes Y (dependent variable) in time; prior levels of M and Y can be controlled.

Statistical Power for Secondary Analyses. For moderator analyses, we will have 80% power detect a Cohen's f^2 of .13 which falls between a small (f^2=.02) and medium (f^2=.15) effect size.[177] In mediation analyses, the indirect effect is the product of 2 regression coefficients and is not distributed normally, which poses a challenge to power calculations.[155] However, Fritz and MacKinnon[209] recommend a bias-corrected bootstrap method for the indirect effect that, in our sample size of 64 sites, would provide 80% power to detect an indirect effect composed of 2 large-sized constituent effects, or a mix of a large-sized and a medium-sized effects.

Qualitative Procedures. We will use qualitative data to provide detailed understanding of response to low- and high-intensity strategies. Specifically, quantitative data from the enhanced non-responder trial will identify 5 categories of response to implementation strategies (**Figure 1**): (1) early responders to low-intensity (by Oct), (2) late responders to low-intensity (by school year end), (3) non-responders to low-intensity, (4) responders to high-intensity, and 5) non-responders to high intensity. Through purposive site visits, we will collect qualitative data within each response type. We expect to target 3 sites per response type to reach a total sample of 15 sites (split across state and study years). We expect to reach saturation with 15 sites, but we are prepared to increase to 20 if needed to reach saturation. During site visits, the research team will conduct semi-structured, key informant interviews with directors and focus groups with educators (4 to 6 educators per Krueger[183,210]). This format is cost-effective and will allow educators to share experiences (independent of directors).[183]

Qualitative Measures. Both director interviews and educator focus groups will probe to provide an in-depth understanding of our proposed moderators and mediators while exploring additional unanticipated ones. Director interviews and educator focus groups will elicit perceived reasons why the strategies worked (or failed) at their site, practical strategies of leadership support, and relevant factors in the implementation climate. **Concepts from the i-PARIHS framework will inform interviews and focus groups guides (Table 4).** Additionally, the research team will capture field notes of the site activities, processes, and interactions that may influence response to the strategies.

Table 4. Sample interview questions by i-PARIHS constructs.

Context	*What is it like to work at this center? How did that influence implementing WISE? How did your leadership get involved?*
Innovation	*Tell me about how WISE worked in your classroom.*
Recipients	*As you implemented WISE, what was most helpful to you? Least helpful?*
Facilitation	*Who was your WISE coach? How did you interact with them? What did the WISE coach do that helped? What do you wish they had done to better support you?*

Qualitative Data Analyses. Qualitative analyses will focus on identifying similarities and differences between site response types. Transcripts will be matched with observed field notes and coded using directed content analysis.[211] **The i-PARIHS framework will provide a template of sensitizing concepts** to label significant, recurrent ideas,[212] particularly ideas that suggest emergent candidate mediators and moderators. We will incorporate inductive codes as we identify additional salient factors.[213] Primary and secondary coders (at least 1 each from AR and LA) will code the same transcripts until inter-rater reliability is established. Minimum reliability will be set at Kappa of 0.75, which reflects excellent agreement between coders.[214] Coding will be independent after establishing reliability. Coders will hold weekly meetings to discuss iterative

expansions to the codebook, to reach consensus about unclear codes, and to document tentative patterns in the data. A third-party team member will resolve disagreements.[215] Participants and stakeholders will review site-level summaries of findings. We will conduct analyses of qualitative interviews yearly and use findings to revise the interview guide for subsequent interviews (e.g., identify probing needs, generate new questions). We will use Nvivo software (QSR International) to code and calculate inter-rater reliability.

Integrating Findings. As we interpret Aim 2 findings, we will connect quantitative and qualitative data. This will include: 1) *expansion* of quantitative findings to provide detail through qualitative data and 2) *complementarity* to deepen understanding and identify other potential moderators and mediators not focused on in quantitative analyses. Thus, qualitative data will explain and elaborate on quantitative findings.

Expected Outcomes. This aim will (1) advance understanding of potential moderators of response to the adaptive implementation strategy and (2) provide insight into mechanisms by which facilitation influences implementation.[181,182] Identifying moderators of response to the implementation strategies provides critical information on what kinds of sites are likely to need high-intensity support from the start, crucial and practical information for future WISE scale-up with the adaptive implementation strategy guide. Further, mediation analyses are described as the "standard for testing theories regarding process."[187] Our random assignment to different facilitation levels embedded in each strategy package, our use of multiple measurements of mediators at key time points, and our multilevel SEM approach will improve causal inference about the relationship between facilitation, the proposed mediators, and the targeted implementation outcomes.[180,208] That is, we are able to provide temporal precedence for the proposed causal chain through randomization; we will control for prior levels of each component in the causal chain.[216] Thus, we expect to provide an important test of the i-PARIHS theory, while illustrating best-practices in mediation analyses in an implementation science study.

In-depth qualitative data will further characterize sites in each response type, allowing the team to refine the decision points of the adaptive implementation strategy guide to be used in future scale-up efforts. These refinements will improve targeted application of strategy intensity to best allocate resources in the future. Further, we may identify strategies used at responder sites that other sites could use. Thus, our study will be one of the first to focus on understanding characteristics of responder and non-responder sites, particularly in ECE. This aim will also uncover factors related to short-term sustainability—qualitative data from this aim and quantitative data on fidelity in the sustainability assessment from Aim 1 will be linked to understand the specific ways low- and high-intensity strategies influence sustainability as well as characteristics of sites that achieve sustainment. According to a recent review,[217] fewer than 25% of funded R01s in Dissemination and Implementation Science studies have evaluated "the impact of a strategy on sustainability."

Potential Problems & Alternative Strategies. First, we may not have selected the most salient moderators and mediators for testing. However, parsimony and power considerations require us to specify theorized moderators and mediators a priori. For moderation, we have focused on two potential moderators with support in the literature and in our prior work. For mediation, we have focused on targets of holistic facilitation to determine if facilitation in the high-intensity strategy activates shifts in the climate and organization as proposed.[71,182] We are not powered for examination of amplification effects (e.g., moderated mediation); nor it is a scientific focus of our study. Qualitative data will explain quantitative findings and elaborate on other potential moderators and mediators. Second, if we do not find significant mediation effects, we can still assess if our strategy failed to produce the desired effects on the proposed mechanisms and/or if the proposed mechanisms failed to produce the desired effects on the targeted implementation outcome.[180] This distinction would inform future work, including strategy selection and theory refinement. Finally, we may identify fewer early responder sites to low intensity strategies than expected. If fewer sites than expected are early responders, we will work with stakeholders to determine key factors associated with non-response.

Specific Aim 3. Assess the incremental cost-effectiveness of the adaptive implementation strategy.

Rationale. Stakeholders need data on cost effectiveness to make informed decisions about resource allocation[218,219] and to prevent widening disparities by promoting implementation strategies that are only feasible in well-resourced settings (e.g., private childcare).[218] Our objective is to determine the incremental cost-effectiveness of the addition of high-intensity implementation strategies on implementation fidelity and child health outcomes relative to continuing low-intensity. Our hypothesis is that the addition of high-intensity strategies at sites that do not respond initially to low-intensity strategies will be cost-effective for improving implementation and child health outcomes. The rationale for this aim is that implementation strategies must be

cost-effective to be useful in the real world. We expect Aim 3 to identify the incremental value of continuing low-intensity strategies vs. augmenting with high-intensity strategies at sites not responsive to low-intensity.

Methods. Cost-effectiveness analysis (CEA) constructs an incremental cost-effectiveness ratio (ICER) to estimate the marginal difference in costs and effectiveness of 2 implementation strategies. We will use CEA to estimate the incremental differences seen with continuing low-intensity strategies versus augmenting with high-intensity strategies on costs and (a) fidelity and (b) child health outcomes.

Measures. We will calculate implementation strategy costs based on time and travel data in the facilitation log and known material purchase costs. Based on work by Ritchie et al.,[220] facilitators will log all activities and travel time using REDCap, which was tested and found feasible in our prior work.

Data Analyses. We will calculate the incremental cost-effectiveness ratio in 4 steps:

Step 1: Aim 1 data will provide estimates of fidelity and child outcome changes (i.e., BMI, RRS, target food consumption) for both study conditions. We will aggregate these findings to the site.

Step 2: Calculate the costs associated with implementation at each site. The WISE intervention cost is the same at all sites, and the ECE system does not accrue downstream costs or benefits. Therefore, we focus on implementation costs only, which comprise 4 categories (**Table 5**). These will be collected using a micro-costing approach, and expenses will be applied to the appropriate site.

Step 3: Estimate covariates to adjust for site-level differences in fidelity. We will use the same covariates as in Aim 1 and aggregate child-level covariates to the site. Incremental costs will be calculated using intent-to-treat analysis to measure the effect of treatment allocation. We will use generalized linear models (GLMs) to estimate the effect of implementation intensity on fidelity, child outcomes, and implementation costs. We will impute missing values via the *ice* procedure in STATA v14.0 (StataCorp LLC). We will compute 2 outcome predictions for each site based on the coefficients from the GLM regressions and the covariates.[219] The first prediction will be as if the site was randomized to the high-intensity strategy, and the second prediction will be as if the site was randomized to the low-intensity strategy. The difference between these predictions represents the incremental effect of the implementation strategy on fidelity, child outcomes, or costs.

Table 5. Implementation Cost, Source, & Estimation Methods

Cost Category	Data Source
Facilitator salary & benefits	Facilitation time tracking log; facilitator salary data from employer records
Facilitator travel expenses	Facilitator travel expense reports
Educational resources	Delivery logs & printing receipts
Other classroom & site resources	Facilitator resource delivery tracking

Step 4: Calculate the incremental cost-effectiveness of adding the high-intensity strategy relative to continuing the low-intensity strategy. The numerator will be the incremental difference in total implementation costs incurred at sites receiving the high-intensity strategy compared to sites continuing the low-intensity strategy. The denominator will include the difference in the changes in fidelity or child outcomes between the fall implementation and spring implementation assessments for high-intensity vs. low-intensity strategies. We will use a nonparametric bootstrap with replacement method with 1,000 replications to generate an empirical joint distribution of incremental implementation costs and fidelity or child outcome change scores, and acceptability curves representing the probability of falling below cost effectiveness thresholds identified by stakeholders (COBRE work to be completed by March 2021). Analysts will build preliminary models using data from the first cohort (Y2) to promote analysis expedience when all three cohorts are completed (Y4).

Expected Outcomes. Aim 3 will provide data on incremental costs for fidelity and child health outcomes. Secondarily, we will explore costs of increasing implementation outcomes of potential interest to future implementers (e.g., acceptability, feasibility). This will inform future scale-up of our adaptive implementation strategy for relevant ECE stakeholders (e.g., education state departments, state and federal Head Start programs). Further, data on the cost-effectiveness of interventions and implementation strategies in ECE programs receiving federal CACFP support (e.g., Head Start) can support policy for these government-funded programs. No available studies in ECE report on implementation strategy costs.[68]

Potential Problems & Alternative Strategies. First, prior studies are unclear on the relationship between early childhood BMI and quality of life, limiting the current study to an estimate of cost per unit of BMI change. While a generalizable measure of effectiveness (e.g., quality adjusted life year), may be preferable for comparison across interventions, it is beyond the scope of this proposal. Second, we chose to focus on costs incurred by the ECE system rather than parents. This is because the ECE system incurs WISE costs primarily, and we are dependent on ECE stakeholders to assess the value of BMI changes attributable to the

intervention. Third, we rely on local stakeholders to identify a cost-effectiveness threshold (our COBRE data) for our implementation strategies given the limited prior research on this topic. While this is supported by recent recommendations on cost-effectiveness research in implementation science,[221] we may not achieve consensus. In this case, we will rely on thresholds identified in similar settings (e.g., schools).

Overall Impact and Future Directions

We expect to provide data on the effectiveness (Aim 1) and cost-effectiveness (Aim 3) of an adaptive implementation strategy for EBP promotion toward obesity prevention in ECE. Further, we will provide stakeholders with data on key leverage points for advancing implementation improvements and on characteristics of sites that are likely to need higher-intensity support (Aim 2). Simultaneously, we will contribute to the science of implementation by providing a test of the i-PARIHS framework in a community setting. We expect these results to have a positive impact because they will provide an evidence base for structuring implementation support in real-world ECE contexts, ultimately providing a guide for applying the adaptive implementation strategy in ECE for WISE scale-up. The results from this study will position us for future research to test the transfer of the adaptive implementation support away from the research team and to the ECE systems. This research path will advance us toward our long-term goal of EBP implementation in ECE to improve diet quality and health outcomes for children.

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