Study Protocol and Statistical Analysis Plan

Official Title: Compliance and Technical Assistance for Child and Adult Care Food Program in Family Child Care Homes

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# 1. PROJECT NARRATIVE

## Introduction

**Goal.** We have a *long-term goal* of reducing the prevalence of childhood obesity prior to kindergarten entry and improving nutritional quality and promoting health for vulnerable children in environments such as child care. Our university-social service partnership, including state departments responsible for overseeing child nutrition and child care programs, proposes the following community-based study of Family Child Care Homes (FCCH). The overall *objective of the proposed research* is to evaluate FCCH compliance with the Child and Adult Care Food Program (CACFP), determine the effectiveness of a technical assistance intervention to improve implementation of CACFP standards and improve nutritional quality of meals and meal environments at FCCH, and implement the Nutrition Technical Assistance Intervention in rural areas. **Specific objectives include:**

1. **Determine compliance of menus and meals in FCCHs with CACFP guidelines.** We will conduct a cross-sectional assessment of FCCH providers' (*n*=52) menus and meals served to children. Observed nutrients and foods will be compared with the CACFP requirements and best-practice recommendations.

**Overview of Needs.** Children who are overweight at the time they enter kindergarten are 4 times more likely to be obese at age 14, with the poorest children at greatest risk.[1] Early prevention in key environments where young children spend substantial time, such as early care and education (ECE) is essential. By 2030, when today's preschoolers are reaching adulthood, the medical costs associated with obesity will be $48-66 billion/year.[2] Primary prevention of obesity is necessary and prioritized to curb exploding medical costs and improve quality of life.[3] This is particularly true in states, such as Oklahoma, that have high obesity and associated health disparities.

**Health Disparities in Oklahoma.** Oklahoma is a diverse state, with 13% of the population reporting American Indian heritage, 9% African American, and 9% Hispanic or Latino.[4] Twenty-three percent of families with children <5 years are living below the poverty threshold.[4] Approximately 1/3 of residents live in rural areas, and 18% are uninsured.[4] Demonstrating a clear disparity in health outcomes, Oklahoma ranks 6$^{th}$ in obesity,[5] 7$^{th}$ in adult diabetes, 2$^{nd}$ in cardiovascular deaths, and 5$^{th}$ in cancer deaths.[6] Low-income preschool children have an obesity prevalence of 14.3%,[7] compared with a national prevalence of 8.9%.[8] Furthermore, ethnic disparities are evident, with young Hispanic and American Indian children having 16-18% higher odds of obesity than their white counterparts.[9] While recent national data suggest that the prevalence of obesity in young children, is on the decline,[10] the prevalence in young children in Oklahoma increased from 13.1% in 2005 to 14.3% in 2010.[7]

**Importance of Early Care and Education (ECE)**. Nationally, 66% of children 3-to-5-year-old children are in non-parental care.[11] Those children with employed mothers spend an average of 32 hours/week, in care which includes center-based ECE, licensed Family Child Care Homes (FCCH), and other friends or relatives.[11] Clearly, the ECE environment is a viable target for obesity prevention[12,13] and has been prioritized by the White House Childhood Obesity Task Force[14] and First Lady Obama's Let's Move campaign.[15] Children attending center-based ECE with healthier environments have healthier weight status.[16] ECE providers are in strategic positions to have a positive influence on obesity-preventing behaviors, like healthy diet.[17,18]

**Nutrition in Early Care and Education (ECE)**. Nutrition received by children in center-based ECE does not meet optimal recommendations;[19-21] children are not eating adequate amounts of whole grains, fruits, vegetables, and nutrients, although energy intake is sufficient.[19-21] Improving nutritional quality for young children is essential to reduce chronic diseases. While dietary quality at ECE may need improvement, ECE meals contain more fruits, vegetables and low-fat milk, and fewer high fat/sugar foods and beverages than meals at home,[22,23] emphasizing the importance of ECE to provide children, especially those living in low-income households, with essential nutrients.

**Federal Child and Adult Care Food Program (CACFP)**. ECE providers serving low-income children can participate in the CACFP, which reimburses qualifying food costs.[24] In 2014, 90% of ECE providers participated in the CACFP,[25] and there were 525.9 million meals served, paying providers $3 billion dollars ($752/child).[26] This underscores the potential reach for improved food consumption for young children. CACFP participation is associated with increased access to nutritious foods.[27,28]

However, there are variations in the fidelity with which the CACFP is implemented; this may compromise overall nutritional quality,[29,30] and leaves substantial room for improvement. The USDA has proposed CACFP modifications for the first time since 1968.[24] In fall 2016, these modifications and best-practices will be implemented nationally. Best-practices include limiting juice and flavored milk, making fruit and vegetable snacks, serving dark vegetables and legumes weekly, and family-style meal service.[24] To highlight the importance of research in this environment, in 2012, the Institute of Medicine (IOM) recommended obtaining a better understanding of FCCH compliance with CACFP.[31]

**Unique Environment of FCCHs**. FCCHs are typically small businesses that care for up to 12 children in the provider's home.[32] Nationwide, there are over 1 million children in FCCH (26% of all ECE attendance).[33] Unlike center-based ECE providers who often employ food-service professionals, FCCH providers prepare all the food served to children in their care, emphasizing the importance of their food preparation and nutrition knowledge. While the majority of FCCH providers have received nutrition training,[34,35] less than half included obesity prevention.[34] It is likely that the majority of nutrition trainings are related to food safety. Most FCCH reported that greater emphasis on the unique needs of FCCH is needed.[36] Few studies have examined child nutrition in FCCH.[29,34,35,37,38] Those studies include self-reported nutrition practices[34,35,37,38] and an evaluation of food receipts.[29] However, no studies have examined the menu quality or observed food consumption of young children attending FCCH. In 2012, IOM expressed the urgent need to understand the obesity-related attributes, specifically nutrition, of the unique environment of FCCHs.[31]

**FCCH Nutrition Training and Intervention**. ECE providers perceive health benefits of nutrition,[39-41] although barriers such as staff knowledge and training diminish the capacity to act.[39,42-44] Two nutrition-focused FCCH interventions have been published.[29,45] In the first intervention, the provision of additional reimbursement funds did increase utilization of fresh produce.[29] However, this approach is not sustainable without increased USDA reimbursement, nor does it address training needs. In the second intervention, self-reported nutrition practices did improve after eight intervention sessions,[45] however the social desirability bias to report changes tempers enthusiasm. In addition to not including an unbiased external evaluator, the intervention did not address specific barriers raised by FCCH providers, including administrative burden and increasing stringency of the CACFP.

**FCCH Provider Barriers**. FCCH may have limited awareness of the importance of superior nutrition. Interviews revealed that while FCCH perceive a high influence on children's health,[34] they desire more training.[35] Our interviewees expressed frustration with CACFP guidelines, and requested more participatory and tailored training to meet their unique needs. FCCH providers are with children, in their home, for the duration of the day, which raises substantial barriers for professional development, training, and interaction with peers.[46,47] Given the current frustration and scheduling limitations for training, complying with new CACFP standards will be challenging for this population of ECE providers.

**Importance of Community-Based Participatory Research (CBPR)**. This proposed research emerged from collaborative efforts and partnerships across the University and two state agencies who are responsible for overseeing the CACFP and ECE licensing and education. A CBPR orientation will guide our partnership, which includes FCCH providers in Oklahoma City (OKC). CBPR, which is the "systematic investigation with the collaboration of those affected by the issue being studied, for the purpose of education and taking action or effecting social change",[48] is a collaborative approach that equitably involves community members and researchers in all phases of the research process, and balances research and action.[49] CBPR can increase the quality of data collection, build community capacity, foster culturally appropriate research, and help in the dissemination and translation of research into policy and practice.[50-53] Dr. Salvatore, who has extensive experience in CBPR,[50,53-56] will provide ongoing guidance and training on this research orientation to our study partnership and students. She will also document our participatory processes.

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## C. APPROACH

**2.C.1. Overview**. To determine the compliance of menus and meals in FCCH with CACFP guidelines (Aim 1), we will conduct a cross-sectional evaluation of a random sample of low-income FCCH providers (*n*=52) participating in CACFP. We will evaluate menus and meals served to and consumed by children. To determine the effectiveness of a community-based Nutrition Technical Assistance Intervention to enhance FCCH providers' meeting CACFP guidelines and best-practices (Aim 2), we will conduct a group-randomized trial of low-income FCCH providers around the OKC metropolitan area. FCCH providers participating in Aim 1 will be randomized to either an intervention group (Section 2.E.2) that will receive the Nutrition Technical Assistance Intervention (*n*=26; Section 2.E.3) or an attention comparison group (*n*=26; Section 2.E.4). Briefly, the Nutrition Technical Assistance Intervention and the comparison group will consist of three encounters with our Intervention team over three months: two home-based visits scheduled at the convenience of the provider and a group class session with other providers. To determine the effectiveness of rural outreach to enhance rural FCCH providers' meeting CACFP guidelines and best-practices (Aim 3), we will conduct a group-randomized trial of low-income FCCH providers (*n*=54) in 6 rural counties in Oklahoma. The County Extension Educator will participate in refinement and lead the Nutrition Technical Assistance (*n*=27; Section 2.E.3) and the comparison intervention (*n*=27, Section 2.E.4). By county, the rural FCCH will be randomized to either treatment (Section 2.E.2). To expand university student opportunities for participation in health research (Aim 4), graduate and professional students will be recruited and trained to implement key elements of this study. Student experiences also include research journal clubs, seminars, and opportunity for professional dissemination.

**2.C.2. Timeline (Table 1).** Annual activities across all aims include, biannual partnership meetings, IRB, protocol, and Intervention training, lay dissemination and manuscript preparation, subsequent grant preparation, student journal club, and evaluation of student experiences. Activities and timelines for each aim are provided in subsequent sections. In year 1, we will begin recruitment of FCCH, complete baseline measures, and begin Intervention implementation. In year 2, baseline data collection will continue and follow-up measures will begin for respective FCCH. Intervention activities will be conducted as FCCH are enrolled. In year 3, Intervention activities in OKC will be completed and follow-up measures will occur. The intervention will be modified for rural outreach with involvement of Extension Educators. In year 4, rural Intervention and baseline measures will be conducted. Follow-up measures will be completed for those rural FCCH enrolled early in the year. In year 5, all rural FCCH follow-up measures will be completed.

Table 1. Study Timeline

| SPECIFIC AIMS AND TASKS | Year 1 | | | | Year 2 | | | | Year 3 | | | | Year 4 | | | | Year 5 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Start-up activities | ■ | | | | | | | | | | | | | | | | | | | |
| Partnership meetings | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | |
| Ethics & IRB training | ■ | | | | ■ | | | | ■ | | | | | | | | | | | |
| Dissemination & manuscript prep | | | | | | | ■ | | ■ | ■ | | | ■ | ■ | ■ | | | | ■ | ■ |
| Grant preparation | | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ | ■ |
| **SPECIFIC AIM 1** | | | | | | | | | | | | | | | | | | | | |
| Recruitment | | ■ | ■ | ■ | | | | | | | | | | | | | | | | |
| Training on measures & protocol | ■ | | | | ■ | | | | ■ | | | | | | | | | | | |
| FCCH observations (Aim 2 baseline) | | ■ | ■ | ■ | ■ | | | | | | | | | | | | | | | |
| Data analyses | | | | | ■ | ■ | ■ | | | | | | | | | | | | | |
| Dissemination & manuscript prep | | | | | | | | ■ | | ■ | | | | | | | | | | |
| **SPECIFIC AIM 2** | | | | | | | | | | | | | | | | | | | | |
| Develop & refine intervention | ■ | ■ | | | | | | | | | | | | | | | | | | |
| Develop protocols & manuals | ■ | ■ | | | | | | | | | | | | | | | | | | |
| Training for interventionists | | ■ | | ■ | | ■ | | ■ | | | | | | | | | | | | |
| Baseline data collection | | ■ | ■ | ■ | ■ | | | | | | | | | | | | | | | |
| Conduct intervention | | | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | | | |
| Intervention fidelity checks | | | | ■ | | ■ | | ■ | | | | | | | | | | | | |
| Follow-up data collection 1 (3 mo. post baseline) | | | | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | | |
| Follow-up data collection 2 (12 mo. post baseline) | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | | | |
| Data analyses | | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | |
| Dissemination & manuscript prep | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | | | | | |
| **SPECIFIC AIM 3** | | | | | | | | | | | | | | | | | | | | |
| Refine intervention for state | | | | | | | | | | ■ | ■ | | | | | | | | | |
| Training for Extension Educators | | | | | | | | | | | | ■ | | | | | | | | |
| Baseline data collection | | | | | | | | | | | | ■ | ■ | | | | | | | |
| Conduct intervention | | | | | | | | | | | | | ■ | ■ | ■ | ■ | | | | |
| Intervention fidelity checks | | | | | | | | | | | | | ■ | | ■ | | | | | |
| Follow-up data collection 1 (3 mo. post baseline) | | | | | | | | | | | | | | ■ | ■ | ■ | ■ | | | |
| Follow-up data collection 2 (12 mo. post baseline) | | | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ |
| Data analyses | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | |
| Dissemination & manuscript prep | | | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ |
| **SPECIFIC AIM 4** | | | | | | | | | | | | | | | | | | | | |
| Recruit students | ■ | | | | ■ | | | | ■ | | | | ■ | | | | ■ | | | |
| Journal club & student seminars | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Student evaluation | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ | | ■ |

**2.C.3. Conceptual Model.** The theoretical framework guiding this study is the Public Health Ecological Model (Section 2.A.11).[57-61] Figure 1 depicts child nutrition and health at the individual level, and the FCCH provider at the institutional level as a key influence on child food consumption. While a reduction in early childhood obesity and improving the dietary intake of young children is the ultimate objective, this study is focused on assessing and intervening at the upstream institution-level (i.e., FCCH provider). Our conceptual model proposes that institutional-level variables, determine CACFP best-practice compliance and, thus, food available to young children. These levels and constituent variables include: the provider's personal nutrition values; knowledge and information (provider level of education, general nutrition knowledge, CACFP knowledge); food and nutrition skills (menu and meal planning skills, food preparation skills, family style meal service, staff nutrition behaviors), and; FCCH characteristics (access to foods, staff employed, children enrolled, years of operation).

**2.C.4. Setting and Participants.** Aims 1 and 2 will take place in and around OKC. Aim 3 will take place in 6 rural counties in Oklahoma (Appendix A). As described in Section 2.A.3., Oklahoma is an ethnically diverse state with substantial health disparities including childhood obesity and poverty.[4,8,9,97]

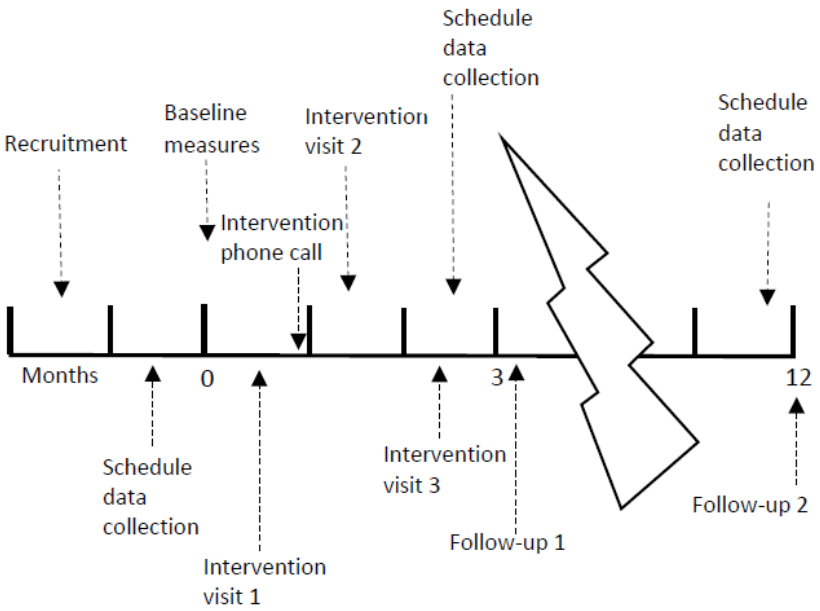
As described in Section 2.A.6., FCCH are small ECE providers who operate out of their homes.[32] FCCH serving low-income children can participate in the CACFP, which provides reimbursement for serving qualifying meals and snacks.[24] In Oklahoma, there are nearly 2,000 FCCH providers;[98] 88% participate in the CACFP.[99] In the OKC-area, there are nearly 160 FCCH providers participating in the CACFP.[100] The 6 selected rural counties have an average of 22 FCCH each, 28.1% of families living in poverty,[4] and 100% of the residents live in small town and rural areas.[101] While the participants in this study are the FCCH providers, food consumption of children enrolled in these FCCH will be observed. Only 2-to-5-year-old children will be eligible for meal observation.

**2.C.5. Partner Involvement and Community Participation with CBPR**. CBPR principles[50,102] will guide our community-university-social service partnership (Section 2.A.10) throughout all phases of the proposed work. While Dr. Sisson has been engaged with ECE community partners since 2010, our current partnership was formalized early in 2015 when our social service partners contacted Dr. Sisson with the aim of conducting community-engaged ECE and health research. Together they identified important community partners (Rainbow Fleet, FCCH providers, FCCH professional organizations, and Extension Educators) and invited Dr. Salvatore, who has extensive experience in both CBPR and children's environmental health, to join the partnership. Partners jointly developed the current proposal, have met regularly and will continue to do so throughout the proposed work. The degree to which partners are involved in the project will vary based on project status and progress. For example, community FCCH providers and Rainbow Fleet will have substantial participation and contribute to the development of the Intervention and suggestions for its implementation. They will have a lesser role in evaluation. However, Extension Educators will have substantial role in the refinement of the Intervention for rural outreach, sustainability, and implementation and a lesser role regarding the earlier objectives. Regular partner meetings will be scheduled and progress will be evaluated. To facilitate participation and attendance the use of teleconference software will be used. Community partners will contribute to the preparation of all dissemination findings and will be encouraged to participate in professional dissemination events.

**2.C.6. Recruitment.** Our ability to recruit ECE providers is demonstrated by our previous work with 25 center-based ECE providers and over 400 children.[21] In addition, we have completed qualitative interviews with center-based ECE providers (*n*=50)[103,104] and OKC area FCCH providers (*n*=30).[83] A total of 46 FCCH providers (see Section 2.D.6 for greater detail) are needed for each Aim 2 (OKC area) and Aim 3 (rural counties). We assume a possible 10% attrition rate, and will recruit 52-54 FCCH providers serving 2-to-5-year-old children from the OKC and rural areas. To participate in the CACFP and receive meal reimbursement funds, FCCH providers must work with a sponsoring organization. We have partnered with Rainbow Fleet, a primary sponsor for Oklahoma, to recruit a random sample of FCCH (see letter). Partnership with our FCCH community partner (see letter) and collaboration with local FCCH professional organizations will also facilitate recruitment and retention. Randomly selected CACFP-participating FCCHs providers will be invited to participate in both the cross-sectional observation (Aim 1) and the Intervention (Aim 2 and 3). Financial incentives will be provided for each observation visit (see Section 2.C.7) and 6 hours of free, prequalified, continuing education credits (half the annual requirement[32]) will be provided for participation in either the Nutrition Technical Assistance Intervention or the comparison group. FCCH have a limited ability to attend professional development.[46,47] Thus, providing flexible, free, convenient training in addition to toolkit materials is a strong incentive. Random assignments to either the Nutrition Technical Assistance Intervention or the comparison group will be generated by the study statistician using the R software. For the rural outreach, FCCH within each county will be randomized. The randomization sequence will be generated in randomly chosen blocks of four and six and will be uploaded and administered using the Research Electronic Data Capture (REDCap) system to ensure that the randomization is concealed.

**2.C.7. Protocol**. Figure 2 presents our protocol time-course. Once participants are recruited into the study, they will be scheduled for cross-sectional measures (baseline). Participants will provide menus and complete self-report measures. Trained research staff will conduct observation of foods consumed and staff meal behaviors before and during lunch. Dr. Sisson will train the measurement team on data collection procedures in lab and field-based settings. Dr. Sisson has experience in the observation of both staff nutrition behaviors[16,77,78,81] and food consumption,[21,22,77,79-81] and has experience training on both measures. Lab-based training will include review of the training protocol and videos prepared by instrument developers, and hands-on training on assessment of food consumption. After lab-based proficiency is established, trainees will work with our FCCH partner for field-based accuracy. Staff will achieve an interrater reliability >0.95 before they are certified for data collection. Random fidelity checks for accuracy by Dr. Sisson will take place throughout the study. Retraining will be conducted as necessary. Annual retraining will still occur if reliability is acceptable (*ICC*≥0.95).

Figure 2. Protocol Time-course for Sample Study Participant




Measurement in OKC will occur before and during lunch on two days that are unknown to the FCCH provider. Rural FCCH will have lunch observed on a single day that is unknown to the provider. FCCH will know the month of the visit and provide 6 "black-out" dates that will not be scheduled. Informational letters will be sent home with children so that parents are aware of the study. Parents can request that their child's meal not be observed by researchers.[16,21,22,77-81,103,105]

Once baseline measurements occur, participants will be randomized to either the Nutrition Technical Assistance Intervention (Section 2.E.3) or the attention comparison group (Section 2.E.4). Both treatments will consist of three sessions with an interventionist. For Aim 2, student research assistants, trained by the investigators, will deliver the Intervention and comparison content to providers. For Aim 3, Extension Educators, trained by the investigators, will deliver the Intervention and comparison content to providers in the same manner as Aim 2. Since FCCH providers are with children in their homes for the entire day, two sessions will be conducted in the provider's home at a convenient time. The third session will be conducted on a weekend day and will consist of a small group class with hands-on opportunities for learning and skills-mastery. Follow-up measures will be conducted at 2 time-points: immediately after the Intervention (3-months post baseline), and a long-term follow-up (12-months post baseline).

## 2.D. Approach Aim 1

**2.D.1. Overview.** This aim will determine the FCCH compliance with existing and proposed CACFP requirements and best-practices. We will conduct a cross-sectional analyses of menus and meals served to and consumed by children in a random sample of low-income FCCH providers (*n*=52). Dietary observations will be evaluated using 1) CACFP food components, such as fruits and whole grains; 2) classification of nutrient-dense foods and; 3) nutrient analyses. Results from this Aim will inform the Nutrition Technical Assistance Intervention. Section 2.C.6. explains recruitment procedures to ensure representation of the OKC-area FCCH population.

**2.D.2. Data Collection**. Measures will be completed before and during lunch on two days (Section 2.C.7) and will be completed at both the child and provider level, consistent with our conceptual model (Section 2.C.3). Outcomes will be self-reported and observed by research staff. See Table 2, for a list of constructs, measures, methods, and ecological level. Participants will be paid $20 for completing cross-sectional measures.

Table 2. Summary and Level of Outcome Measures

| Institutional Level (FCCH Provider) | | Individual Level (2-to-5-year-old child) | |
|---|---|---|---|
| Demographic characteristics<br>• Size<br>• Years of operation<br>• Number of staff | Self report demographic questionnaire | Food consumption<br>• Plate waste | Observation |
| Knowledge & Information<br>• Provider education<br>• General nutrition knowledge<br>• CACFP knowledge | Self report questionnaires | | |
| Food and Nutrition Skills<br>• Family style meal service<br>• Staff nutrition behaviors<br>• Food preparation<br>• Menu & meal planning | Self report questionnaires<br>Observation<br>Menu assessment | | |
| Provider values and interest in nutrition | Self report questionnaire | | |

**2.D.3. Provider-Level Measures.** Several provider-level outcomes will be collected, as follows.

*Demographic characteristics.* Providers will report FCCH characteristics.

*Knowledge & Information*. Providers will report their highest level of education and previous nutrition training. Provider nutrition knowledge will be assessed with the Revised General Nutrition Knowledge Questionnaire, which takes 15 minutes to complete and is a valid and reliable instrument (Appendix B).[106] Providers will report their knowledge of current and proposed CACFP requirements and best-practices (Appendix C).

*Food and Nutrition Skills.* Providers will report food and nutrition practices and staff behaviors using the Nutrition and Physical Activity Self Assessment (NAPSACC), revised for FCCH (Appendix D).[107,108] Dr. Sisson has previously used NAPSACC.[76] The NAPSACC has been validated,[107] used in numerous ECE interventions,[62] and is expected to take 10 minutes to complete. Key items of interest include the self-reported frequency of serving fruit, vegetables, vegetables with deep color, high-fiber and whole grains, high-sugar and high-fat foods, juice, and milk, meal service style, and role modeling fruit and vegetable consumption.[108]

Research staff will observe food and nutrition skills using the Revised Environmental and Policy Assessment Observation (EPAO; Appendix E)[109] and the Meal Observation worksheet (Appendix F) of the Wellness Child Care Assessment Tool (WellCCAT).[110,111] Dr. Sisson has proficiency with the EPAO[16,81] and will conduct and certify all measurement staff (Section 2.C.7). We will only be utilizing those EPAO components related to staff nutrition behavior (modeling, encouragement), meal service style, foods served, food preparation methods, and nutrition-related policies.

FCCH menus will be obtained and evaluated for 1) CACFP food components, such as fruit and whole grains; 2) classification of nutrient-dense foods,[79-81,105] and; 3) software-based nutrient analyses using FoodWorks® Nutrient Analysis Software and the USDA food database. Recipes and meal preparation style will also be ascertained from the FCCH provider, typically the food preparer, to enhance the quality of the nutrient analyses. We will examine one week of meals from the menu and impute serving size to minimum CACFP serving, if not provided.[29,36,82,112,113] We will determine nutrient-dense foods (Appendix G for data sheets) by their presence rather than quantities, since serving sizes vary dramatically between different foods; a food will be counted as one serving for any amount served, rather than using actual serving sizes.[110,111] The Preschool Menu Review Sheet (Appendix H) from WellCCAT will also be used to classify foods into categories.[110,111] To ensure data integrity and quality control, a random 10% of menus will be evaluated by a different research staff member.

**2.D.4. Child-Level Measures.**

*Food consumption*. Dietary observations will be conducted used the Dietary Observations in Child Care (DOCC; Appendix I);[114] a technique used by our team[21,77,79,80] with high inter-rater reliability (*ICC*=0.968, $p<0.001$). Each visit, a maximum of three eligible children will be observed and averaged for the FCCH. OKC-area FCCH will have 2 lunch observations while rural FCCH will have a single observation. Observed plate waste has been reported to be an accurate method ($r$=0.90-0.95) with

which to measure food consumption when compared with measured plate waste.[115] Trained research staff (Section 2.C.7.) will record food (quantity, type, details) served and food left on the plate after the meal. Food consumption will be described similarly to menus (Section 2.D.3). While research staff will be at the FCCH before lunch, many providers prepare meals before or after hours and refrigerate them for ease of meal preparation when children are present.

**2.D.5. Data Management.** Study data will be managed using REDCap electronic data capture tools hosted at the University of Oklahoma Health Sciences Center.[116]

**2.D.6. Statistical Analyses and Power.**

*Sample Size Determination*. Estimates of adherence to dietary guidelines were derived from the Early Childhood Longitudinal Study among 4-year-old children who attend CACFP-participating center-based ECE.[17] Table 3 includes an estimate of the sample size required to estimate the percentage of FCCH providers who are adherent within ±15% assuming a two-sided 0.05 alpha level. Based on these estimates, 46 FCCH providers are needed. Assuming possible 10% attrition, a target sample size of 52 will be used, resulting in an estimated 130 children (2-3 children/FCCH) nested within the FCCH.

**Table 3: Sample size required to estimate the percentage of FCCH providers who are adherent to recommended guidelines to within ±15% assuming a two-sided 0.05 alpha level**

| Food Item | Assumed Adherence Proportion | Required Sample Size |
|---|---|---|
| Milk 2+ cups/day | 0.73 | 34 |
| Vegetables 2+ servings/day | 0.40 | 41 |
| Fruit or Juice 3+ servings/day | 0.54 | 43 |
| Sodas ≤ 1 – 3 servings/week | 0.57 | 42 |
| Salty Snacks ≤ 1 – 3 servings/week | 0.59 | 42 |

*Statistical Analyses.* **Aim1: Determine compliance of menus and meals in FCCHs with CACFP guidelines.** Descriptive statistics will be used to summarize sample characteristics. The proportion of FCCH providers who are adherent to CACFP guidelines will be estimated and 95% confidence intervals will be calculated based on the binomial distribution. To control the inflation of the type I error, a small number of primary measures has been identified, with all other measures of secondary interest. The primary measures of interest are the proportion 1) offering fruit two times per day or more; 2) offering vegetables two times per day or more, with at least one being dark green, orange, red, or deep yellow; 3) offering high-fiber, whole grain foods two times per day or more; 4) offering high-sugar, high-fat foods less than one time per week or never; 5) offering 4-6 oz. serving of 100% fruit juice two times per week or less; 6) and offering low-fat (1%) or fat-free (skim) milk. As an exploratory analysis, log-binomial regression modeling[117] will be used to estimate the association, quantified using a prevalence proportion ratio, between adherence outcome measures and provider characteristics, including age, race, ethnicity, and education level where proportions are used to summarize center-level demographic characteristics for purposes of regression modeling. Dietary intake, collected at the child level, will be descriptively summarized for the entire sample using generalized linear mixed effects modeling to account for the clustering of children within FCCH.[118] Generalized linear mixed effects modeling will be used to summarize the mean quantities of intake (outcome measure) as a function of independent factors including provider age, race, ethnicity, and education level to generate hypotheses regarding the association between provider characteristics and dietary intake measures. The cluster, FCCH, will be modeled as a random effect, while all other independent factors will be modeled as fixed effects. Residual diagnostics will be evaluated to assess model fit and transformations will be used to address non-normality or non-constant variance of the residual values. In all analyses, sex as a biologic variable will be considered. The sex of the child and the FCCH provider will be included in the regression models as an effect modifier, interaction term, and, in addition, estimates will be calculated for samples stratified by the sex of the child and the sex of the FCCH provider. These analyses will be exploratory, as the study is not powered to detect modification by sex.

**2.D.7. Expected Outcomes.** It is anticipated that outcomes from the successful completion of Aim 1 will include meeting IOM priority research areas to better understand foods served to children in FCCH participating in the CACFP[13,31] and developing a necessary foundation for current diet and FCCH staff behaviors. Specifically, we will know about FCCH general nutrition and CACFP knowledge. We will determine FCCH staff nutrition behaviors based on self-report and meal observation by the measurement team. We will have objective assessment and nutrient quality evaluation of the menu

and actual foods to determine CACFP best-practice compliance. This information will be valuable for informing and shaping the Nutrition Technical Assistance Intervention described in Aims 2 and 3.

**2.D.8. Use of Results.** The immediate use of the results of Aim 1 will be to inform the Nutrition Technical Assistance Intervention. Results will be provided, in aggregate, to the FCCH providers, Child Nutrition Services Division of the Department of Education, and the CACFP sponsoring organizations. Lay and general dissemination of these findings will occur at local venues, such as FCCH professional organizations. These results can be used by the providers and lay stakeholders to understand the nutrition environment and foods available in FCCH. Results will also be used for scientific dissemination in peer-reviewed manuscripts in addition to presentations at nutrition-focused conferences, including the National CACFP Sponsors Association and the CACFP Conference.

**2.D.9. Specific Timeline**. The general study timeline is in Table 1. (Section 2.C.2). Activities and deliverable outcomes specific to Aim 1 are depicted in Table 4.

**Table 4. Specific Timeline and Deliverable Outcomes: Aim 1**

| Dates | Activity | Deliverable Outcome |
|---|---|---|
| September 2016 | Initial stakeholder meeting | Notes and minutes of that meeting |
| October-November 2016 | Training on measures and protocol | Manual of Procedures |
| | Recruit graduate and professional students | Certificate of ethics training completion |
| November 2016-June 2017 | Recruit OKC-area FCCH Collect self-report surveys and meal observations | |
| February 2017 | | Biannual progress report for stakeholders |
| July-September 2017 | Data management | |
| September 2017 | | Biannual progress report for stakeholders |
| October 2017-December 2017 | Data analyses | Submit preliminary abstracts |
| January 2018-March 2018 | Lay dissemination and manuscript preparation | Final data abstract submission |
| July 2018 | | Presentation at CACFP conference |

## 2.E. Approach Aim 2

**2.E.1. Overview.** This aim will determine the effectiveness of a community-based Nutrition Technical Assistance Intervention designed to enhance meeting CACFP guidelines and best-practices. We will conduct a group randomized trial to test the hypothesis that participation in the Nutrition Technical Assistance Intervention will enhance FCCH knowledge of CACFP requirements and best-practice recommendations, staff nutrition practices, children's food consumption, and enhance CACFP best-practice compliance compared with the group receiving the comparison. Results from this aim will address the IOM call for increased nutrition research in FCCH,[13,31] demonstrate effectiveness of our proposed Intervention, and provide key information for scaling up implementation. Recruitment procedures (Section 2.C.6.) will ensure representation of the OKC area FCCH population.

**2.E.2. Intervention Overview.** Participating FCCH providers in and around the OKC area will be randomized to either the Nutrition Intervention (*n*=26), or an attention comparison group (*n*=26) that will receive an Integrated Pest Management intervention with the same format and visit frequency. Briefly, the Nutrition Technical Assistance Intervention and comparison group will consist of three encounters with our intervention team: two home-based, 90-minute visits scheduled at the convenience of the FCCH provider and a 3-hour group class session that will be conducted on a weekend. Total contact time with intervention staff will be 6 hours. All participants will receive a toolkit. FCCH providers will complete either intervention over a period of three months. Outcome measures will be taken at three time points: (1) baseline, 2) immediately after the Intervention (3-months post baseline), and 3) a long-term follow-up (12-months post baseline). Section 2.C.7 describes the protocol. Figure 2 provides a timeline for study activities.

**2.E.3. Intervention Strategies.** The theoretical foundation for this Intervention is described in Section 2.A.11). Table 5 lists model constructs and parallel intervention activities. Our formative work and guidance from community partners have directly informed the Intervention module content and

delivery modes. Additional target areas will be identified during the quantitative evaluation of meals served and FCCH food practices (Aim 1).

All providers will receive shared, core modules. Consistent with adult learning practices[69] and self-determination theory,[68] participants will select elective modules. All modules are designed to be independent units. Individual sessions will be conducted in the FCCH provider's home at a convenient time. Consistent with developing social support,[67] the group session will be conducted on a weekend day and will consist of a cooking class in which participants will experience hands-on practice with healthy, inexpensive recipes that meet CACFP best-practices. Participants will take home recipes and meal service equipment for family-style meals. The cooking class will be conducted in the OUHSC Department of Nutrition's state-of-the-art teaching kitchen, with convenient and free parking.

Table 5. Model Constructs and Parallel Intervention Activities.

| Model & Construct | Intervention Activities |
|---|---|
| **Social Cognitive Theory** | |
| Behavioral capability | Educational lessons, hands-on activities, cooking class |
| Self-control | Goal setting, problem solving, goal progress evaluation |
| Expectancies (value of outcome) | Educational lessons integrated with qualitative teacher self-perspectives |
| Observational learning | Hands-on activities, cooking class, community partner involvement |
| **Self Determination Theory** | |
| Proactive | Elective modules, hands-on activities |
| Personal importance | Educational lesson integrated with qualitative teacher self-perspectives |
| Interest | Hands-on activities |
| **Adult Learning Principles** | |
| Active Learning | Elective modules, hands-on activities |
| Preconceptions | Reflective listening |
| Understanding | Educational lesson includes "why" |
| Self-assessment | Goal setting, progress check, troubleshooting |
| Community-centered | Small group cooking class |
| **Social Support** | |
| Instrumental support | Hands-on activities, cooking class |
| Informational support | Educational lessons, goal setting, trouble shooting |
| Appraisal support | Goal progress, troubleshoot |
| Peer support | Small group cooking class |

Individual sessions will each last 90 minutes and consist of 4 20-minute modules (See Table 6 for proposed module topics), followed by a 10-minute wrap-up and discussion. Each module will be delivered in the following order: 7-to-10 minute lesson, 5-to-8 minute activity, and 5-to-8 minute reflection and goal setting. The interventionist will provide the educational material, lead the activity, and engage in reflective listening and guide the participant through goal-setting. The 4 core modules will be delivered in the 1st individual session. Between the individual sessions, the interventionist will call the provider to assess goal progress and trouble-shoot. The elective modules will also be selected. The 2nd individual session will begin with a brief discussion of goal progress, followed by delivery of 4 elective modules. The small group cooking class will last 90 minutes, the first 20 minutes dedicated to welcome and content delivery, 60 minutes for cooking and practice with family-style meal service, and the final 10 minutes for discussing the benefits of family-style meals and providing final wrap-up.

Table 6. Proposed Module Topics

| Core Modules | Elective Modules | Cooking Class |
|---|---|---|
| 1. SMART goals<br>2. Why meet best practice<br>3. Portion distortion: What's the right size<br>4. Staff behaviors: Leading the way | 1. A healthier daily sheet<br>2. Communicating with parents<br>3. Nutrition facts<br>4. Food eligibility<br>5. Menu and meal planning<br>6. Picky eating<br>7. Food aversion<br>8. Lowering costs<br>9. More than meal assembly<br>10. Serve more fruits & veggies<br>11. Cooking across the rainbow<br>12. A fluid situation | 1. Making family style work for you<br>2. Best practice recipes<br>3. Meeting best practices<br>4. Shopping local |

All participants will be provided with a toolkit of materials (Appendix J for samples), supplies, and resources to be provided at each session. Materials include all educational content (including content for electives not selected), goal setting sheets, sample materials to send home to parents, visual aids and nutrition toys, and family-style meal service equipment.

**2.E.4. Attention Comparison Group.** The attention comparison intervention in Integrated Pest Management (IPM) will be matched to the Nutrition Technical Assistance Intervention for time and exposure. IPM aims to reduce the use of pesticides and subsequent child exposure to potentially harmful chemicals at FCCH. Co-Investigator Dr. Salvatore, who has extensive experience developing and evaluating community-based interventions to reduce children's exposure to pesticides, will lead the development and implementation of the IPM intervention.[84-86,119] With input from all partners, Dr.

Salvatore will adapt the IPM Toolkit for FCCH[120] and the IPM: A toolkit for ECE programs developed by her colleagues at the California Childcare Health Program at the University of California San Francisco[121] for Oklahoma FCCH. IPM will also include a toolkit of educational materials and supplies). Data collection will mirror that of the main Intervention, with some additional measures to be collected.

**2.E.5. Intervention Implementation Evaluation.** The evaluation of the Intervention will follow the RE-AIM framework (Section 2.A.9) and include assessment of the intervention's reach, effectiveness, adoption, implementation, and maintenance.[70,71] To ensure fidelity to the protocol, all interventionists will be trained by either Dr. Sisson and Chef Poe (Nutrition Intervention) or Dr. Salvatore (comparison group). In-person training will be complemented by an interventionist manual. Training will include hands-on and practice opportunities. Interventionists must participate in all training sessions. A checklist of intervention activities for each session will be developed and completed immediately after individual sessions to determine the percent of content delivery. After each session, the interventionist will log any issues to be discussed at the next weekly team meeting. Field intervention fidelity checks will be conducted biannually (Timeline Section 2.C.2 and Table 1). All interventionists will participate in retraining biannually, with more frequent retraining as necessary. Records of protocol changes and deviations will be recorded and reported.

**2.E.6. Recruitment and Retention.** Recruitment strategies for Aim 2 are the same as described in Section 2.C.6. Our CBPR partnership will be essential in retention efforts. Briefly, we will recruit a random sample of low-income FCCH providers participating in the CACFP from the OKC area. Partnership with the CACFP sponsoring organization responsible for this area will ensure adequate representation of the population. As suggested by community partners, free and convenient continuing education will promote retention. A toolkit of resources valued at $250 will be provided to participants over the course of the Intervention and comparison. Given that some attrition is likely, we will enroll more participants than needed (Section 2.E.10). Participants will also receive $30 and $40 for completion of follow-up data collection at 3-months and 12-months post baseline, respectively.

**2.E.7. Outcome Measures.** Outcome measures will be taken at three time points (Section 2.C.7. and Figure 2): 1) baseline, 2) immediately after the intervention (3-months post baseline), and 3) a long-term follow-up (12-months post baseline). Data collection procedures (Section 2.D.2), provider-level measures (Section 2.D.3.), and child-level measures (Section 2.D.4) are described above. Table 2 summarizes the conceptual model construct and outcome measure. Selected outcome measures[122] for our comparison group will also be included at each time point to inform future IPM and other children's environmental health interventions for FCCH and other ECE settings in Oklahoma.

*Primary measures.* Primary outcome measures represent provider-level knowledge and information and food and nutrition skills, and child-level food consumption. The primary knowledge outcome will be knowledge of CACFP best-practices. Food and nutrition skills will be primarily examined using the EPAO staff nutrition behaviors (Appendix E) and menu compliance with CACFP best-practices, as determined by number of food components and number of servings of nutrient-dense foods based, on the WellCCAT preschool menu review (Appendix H). Primary child-level food consumption will be assessed in the same manner as the menu.

*Secondary measures.* Secondary measures will be collected to further examine the knowledge and information gained and the application of those food and nutrition skills. Secondary measures include general nutrition knowledge (Appendix B), family-style meal service, WellCCAT-determined staff nutrition behaviors (Appendix F), observed food preparation methods, self-reported NAPSACC nutrition practices (Appendix D), self-reported provider interest in nutrition, and nutrient analyses of the menu and meals served and consumed.

*Evaluation of Intervention Costs.* Given the current fiscal crisis across governments, it is mandatory to report not only on whether a proposed intervention works, but also the costs related to it and their relationship. While very little is known about the cost of conducting an obesity prevention intervention in the ECE setting, empirical data are inexistent for FCCH.[93] Resource allocation will be reported using the implementation costs approach, since the Intervention is provider-level. The economic evaluation will provide the elements of a cost-effectiveness analysis, in which the costs of the Intervention will be addressed and compared with likely gains in children's health estimated from empirical data available

on obesity prevention programs. This will illustrate the relationship between costs and potential benefits of the Intervention and inform replication and scale-up.

Monetary costs of the proposed study will be defined as the dollar amount spent on development and implementation. One-time costs, such as project planning and design, will not be included, as they would not be incurred subsequently. Using a societal perspective,[123] discounted direct and indirect costs over the three years of the project will be reported. Major cost categories will include personnel, including salaries, benefits, and in-kind contribution; materials; travel costs, to and from the FCCH; administrative costs, and; other costs related to participant recruitment/incentives. Because participants will keep all Intervention materials and equipment and the Intervention will largely be conducted in their homes, with all sessions prequalified as licensing-required continuing education credits, indirect costs to participants are expected to be minimal and will not be considered in the calculations. Following the U.S. Office of Management and Budget's recommendation, a Marginal Excess Burden will be included in the direct costs calculations.[124]

The outcome benchmarks against which we will compare the Intervention costs will be specific for the study age group, i.e., preschool children, and will include only those that accounted for significant changes in body mass index.[125] Multiple effectiveness estimates will be used to show a range of cost-effectiveness ratios, with the cost per estimated unit of BMI reduction used as the final unit of analysis.

**2.E.8. Data Management.** Aim 2 is the same as Aim 1, and is described in Section 2.D.5.

**2.E.9. Analytical Approach**. The unit of randomization will be the FCCH provider; all child-level outcomes will be analyzed as per the provider-level randomized assignment. An intention-to-treat paradigm[126] will be followed in which data from all eligible participants are analyzed according to randomized Intervention assignment, regardless of adherence. A secondary, per-protocol analysis will be performed in which data from providers who attended at least 2 of the 3 sessions will be included.[127] Baseline sociodemographic characteristics will be summarized after stratifying by Intervention assignment. Comparisons in outcomes will be made between Intervention groups using generalized linear mixed models to account for the correlation among measures made on the same provider over time and measures made on children nested within FCCH.[118] FCCH and child will be modeled as random effects. A log-binomial model[117] will be fit for dichotomous outcomes, to measure the prevalence proportion ratio for outcomes like practices relative to a specific food type, and a linear model will be fit for continuous outcomes to estimate the difference in means between groups, such as mean knowledge scores. Time by intervention interactions will be used to estimate the effect of the Intervention program on outcomes over time. Non-linear time trends will be considered and modeled using categorical time variable coding. Baseline assessments of the outcome measures will be included in the model as possible confounding factors.[128] Comparisons between the Intervention and attention comparison groups will be made after stratifying by follow-up time point if a significant time by Intervention effect is detected. Missing data will be imputed using multiple imputation techniques.[129] Sex as a biologic variable will be examined as described in Aim 1.

**2.E.10. Power**. Section 2.D.6 describes the primary analysis upon which power was determined. This resulting sample size, a total of 46 FCCH providers (23 per group), provides sufficient power to address Aim 2. The target size of 46 providers will provide 80% power to detect a difference between the Intervention and control groups of 40% adherence for the control versus 80% adherence among the Intervention for a particular food serving at the final time point assessment, or similarly, menu compliance with CACFP best-practices as an endpoint, assuming a 2-sided 0.05 alpha level. The targeted sample size will result in 80% to detect a difference in mean CACFP best-practice knowledge score that is 85% as large as the standard deviation, a "large" effect in the language of Cohen, assuming a 2-sided 0.05 alpha level.[130] For child-level measures, assuming that there are two to three eligible children at each center on the observation date, the target sample size of 46 FCCH and 115 children will result in greater than 80% power to detect a difference in intake of a particular food type, based on the child-level food consumption as described above, between the Intervention and control groups of 33% in the control group versus 65% in the Intervention, assuming a 2-sided 0.05 alpha level and a within-center correlation of 0.3. A target sample size of 52 (26 per group) will be used to account for an

assumed 10% attrition rate, resulting in an estimated 130 children nested within the FCCH. Sample size calculations were conducted using PASS software.[131,132]

**2.E.11. Expected Outcomes.** Aim 2 includes the implementation and refinement of the Intervention in advance of Aim 3 which focuses on rural outreach and extension. Analyses of menus for compliance with CACFP guidelines and best-practices and observations of lunch meals will provide objective assessment of actual CACFP recommendations and best-practice compliance in OKC-area FCCH. These observations will fill a gap in the knowledge of what is actually consumed by children in FCCH in Oklahoma and will also reveal specific "problematic" meal components and/or staff behaviors to be targeted in FCCH interventions to improve child nutrition.

**2.E.12. Use of Results.** Immediate use of the results of Aim 2 will be to inform the implementation of the Nutrition Technical Assistance Intervention in selected rural counties in Oklahoma. Individual FCCH will be provided with a report of their results which can be used for self-evaluation. Results, in aggregate, will be provided to the Child Nutrition Services Division of the Department of Education, and the CACFP sponsoring organizations. Aggregate results will be disseminated at local venues, such as FCCH professional organizations. Results will also be used for scientific dissemination in peer-reviewed manuscripts and presentations at nutrition-focused conferences including the Society of Nutrition Education and Behavior and the International Society for Behavioral Nutrition and Physical Activity.

**2.E.13. Specific Timeline.** The general timeline for the entire study is in Table 1 (Section 2.C.2); activities and deliverable outcomes specific to Aim 2 are depicted in Table 7.

**Table 7. Specific Timeline and Deliverable Outcomes: Aim 2**

| Dates | Activity | Deliverable Outcome |
|---|---|---|
| September 2016 | Initial stakeholder meeting | Notes and minutes of that meeting |
| October-November 2016 | Intervention development | Intervention Manuals (Nutrition Intervention and Attention Comparison) Intervention Toolkits (Nutrition Intervention and Attention Comparison) |
| January 2017 | Interventionist training | |
| November 2016-June 2017 | Recruit OKC-area FCCH Collect self-report surveys and meal observations | |
| February 2017 | Stakeholder meeting | Biannual progress report for stakeholders |
| April 2017-August 2018 | Conduct Intervention | |
| July 2017 | Intervention fidelity check | Fidelity progress report |
| July 2017-September 2018 | Collect self-report surveys and meal observations (3-month Intervention follow-up) | |
| September 2017 | Stakeholder meeting | Biannual progress report for stakeholders |
| July 2018-March 2019 | Data management and data analyses | Submit preliminary abstracts |
| February 2018 | Stakeholder meeting | Biannual progress report for stakeholders |
| May 2019 | | Presentation at International Society of Behavioral Nutrition and Physical Activity Conference |
| April 2018-February 2019 | Collect self-report surveys and meal observations (12-month Intervention follow-up) | |
| September 2018 | Stakeholder meeting | Biannual progress report for stakeholders |
| February 2019 | Stakeholder meeting | Biannual progress report for stakeholders |
| April 2019-March 2020 | Data management and data analyses | Submit preliminary abstracts |
| September 2019 | Stakeholder meeting | Biannual progress report for stakeholders |
| January 2019-January 2020 | Lay dissemination and manuscript preparation | Final data abstract submission Manuscript submission |
| February 2020 | Stakeholder meeting | Biannual progress report for stakeholders |
| July 2020 | | Presentation at Society of Nutrition, Education, and Behavior conference |

## 2.F. Approach Aim 3

**2.F.1. Overview.** This aim integrates sustainable extension efforts to determine the effectiveness of the implementation of a rural outreach Nutrition Technical Assistance Intervention designed to enhance meeting CACFP guidelines and best-practices. Similar to Aim 2 (Section 2.E.1), we will conduct a group randomized trial to test the hypothesis that participation in the Nutrition Technical Assistance Intervention will enhance FCCH knowledge of CACFP requirements and best-practice recommendations, staff nutrition practices, children's food consumption, and enhance CACFP best-practice compliance compared with the group receiving the comparison intervention. The Intervention will be refined

following completion of OKC-area implementation based on findings from implementation of Aim 2 and for rural outreach with direction from the Extension Educators. Results from this Aim will address the IOM call for nutrition research in FCCH,[13,31] demonstrate effectiveness of our proposed Intervention, and provide key information for scaling up implementation. Recruitment procedures (Section 2.C.6) will ensure rural representation of FCCH in 6 selected counties.

**2.F.2. Intervention Overview.** The rural outreach will include 54 FCCH providers in 6 counties (~9 FCCH in each). The FCCH in each county will be randomized to either the Nutrition Intervention (*n*=4-5/county *n*=27 total) or comparison group (*n*=4-5/county *n*=27 total) with the same format and visit frequency. Randomization will be stratified by county. Section 2.C.7 describes the protocol. Section 2.E.2 provides an Intervention overview. The rural outreach Intervention will follow the identical timeline, schedule, and activities presented in Aim 2. Figure 2 provides a timeline for study activities.

**2.F.3. Intervention Strategies.** Intervention strategies for rural outreach implementation of the Nutrition Technical Assistance Intervention will be identical to those presented in Section 2.E.3. Extension Educators will be involved in refining the Intervention for rural implementation and sustainability. Table 5 lists model constructs and parallel Intervention activities. See Table 6 for proposed module topics.

**2.F.4. Attention Comparison Group.** The attention comparison intervention will be identical to that which is presented in Section 2.F.4 and will include a time-matched Integrated Pest Management (IPM) intervention. Data collection will mirror that of the main Intervention, with some additional measures to be collected (Section 2.E.7).

**2.F.5. Intervention Implementation Evaluation.** The evaluation of the Intervention will follow the RE-AIM framework[70,71] (Section 2.A.9) and is also described in Section 2.F.5. Field Intervention fidelity checks will be conducted biannually (Timeline Section 2.C.2 and Table 1).

**2.F.6. Recruitment and Retention.** Recruitment strategies for Aim 3 are the same as described in Section 2.C.6 and 2.E.6 (Aim 2). Our CBPR partnership, especially Extension Educators, will be essential in retention efforts. Briefly, we will recruit a random sample of low-income FCCH providers participating in the CACFP from 6 rural counties. Given that some attrition is likely, we will enroll more participants than needed (Section 2.E.10). Financial incentives are described in Section 2.F.6.

**2.F.7. Outcome Measures.** Outcome measures will be taken similarly to Aim 2, at three time points (Section 2.C.7. and Figure 2): 1) baseline (Aim 1), 2) immediately after the Intervention (3-months post baseline), and 3) a long-term follow-up (12-months post baseline). Data collection procedures (Section 2.D.2), provider-level measures (Section 2.D.3), and child-level measures (Section 2.D.4) are described above. Table 2 summarizes the conceptual model construct and outcome measure. Section 2.F.7 describes the primary and secondary outcomes and associated Appendices for instruments.

**2.F.8. Data Management.** Aim 3 is the same as Aim 1 and 2 and is described in Section 2.D.5.

**2.F.9. Analytical Approach**. Identical to Aim 2 (Section 2.E.9), with the adjustment for the design variable, county, in the modeling

**2.F.10. Power**. Section 2.D.6 and 2.F.10 describe the primary power analysis. The attrition rate is assumed to be 15% for the rural outreach program and therefore, the total target sample size is increased to 54 FCCH providers.

**2.F.11. Expected Outcomes.** Aim 3 focuses on rural outreach and extension of a Nutrition Technical Assistance Intervention in selected rural counties. Expected research outcomes are similar to Aim 2 (Section 2.E.11), with the application to rural counties. Involvement of outreach and Extension Educators to enhance access quality nutrition technical assistance will inform statewide implementation and address rural health disparities. Information necessary to scale-up the Intervention for statewide dissemination is an expected outcome.

**2.F.12. Use of Results.** Immediate use of the results of Aim 3 will be to inform the sustainable, statewide implementation of the Nutrition Technical Assistance Intervention across Oklahoma and to attain subsequent research grant funding. Individual FCCH will be provided with a report of their results which can be used to further self-evaluation. Results, in aggregate, will be provided to the Child Nutrition Services Division of the Department of Education and the CACFP sponsoring organizations. Aggregate results will be disseminated at local venues such as FCCH professional organizations. Results will also

be used for scientific dissemination in peer-reviewed manuscripts and presentations at nutrition-focused conferences, including Experimental Biology and Annual Extension Conferences.

**2.F.13. Specific Timeline.** The general study timeline is in Table 1 (Section 2.C.2). Activities and deliverable outcomes specific to Aim 3 are depicted in Table 8.

**Table 8. Specific Timeline and Deliverable Outcomes: Aim 3**

| Dates | Activity | Deliverable Outcome |
|---|---|---|
| February 2019 | Refine intervention for rural outreach | Intervention Manuals (Nutrition Intervention and Attention Comparison)<br>Intervention Toolkits (Nutrition Intervention and Attention Comparison) |
| August 2019 | Interventionist training | |
| August 2019-January 2020 | Recruit rural FCCH<br>Collect self-report surveys and meal observations | |
| September 2019 | Stakeholder meeting | Biannual progress report for stakeholders |
| October 2019 to September 2020 | Conduct Intervention | |
| December 2019 & June 2020 | Intervention fidelity check | Fidelity progress report |
| January 2019-December 2019 | Collect self-report surveys and meal observations (3-month Intervention follow-up) | |
| February 2020 | Stakeholder meeting | Biannual progress report for stakeholders |
| April 2020-June 2021 | Data management and data analyses | Submit preliminary abstracts |
| September 2020 | Stakeholder meeting | Biannual progress report for stakeholders |
| October 2020 | | Presentation at Experimental Biology conference |
| October 2020-September 2021 | Collect self-report surveys and meal observations (12-month Intervention follow-up) | |
| February 2021 | Stakeholder meeting | Biannual progress report for stakeholders |
| October 2020-May 2021 | Data management and data analyses | Submit final abstracts<br>Manuscript submission |
| September 2021 | Stakeholder meeting | Biannual progress report for stakeholders |
| October 2020-September 2021 | Lay dissemination and manuscript preparation | Final data abstract submission<br>Manuscript submission |
| July 2021 | | Presentation at Annual Cooperative Extension Conference |

## 2.G. Approach Aim 4

**2.G.1. Overview.** The objective of this aim is to expand university student opportunities for participation in health research. This proposed study will provide meaningful opportunities for interdisciplinary professional and graduate students to participate in a multi-level CBPR intervention. *We anticipate increased interest in science and research careers as a result of this increased opportunity.*

**2.G.2. College Environment and Mentorship.** The College of Allied Health at OUHSC and the College of Human Sciences at OSU have diverse student populations, including groups that are traditionally underrepresented in biomedical and health research. Allied Health student demographic data indicate that approximately 83% of the students are female, and 23% are from non-white ethnic groups. Native American (4.6%) students are the predominant minority group represented. Human Sciences graduate student demographic data indicate that approximately 80% of the students are female and 40% are international or non-white ethnic groups. The Behavioral Nutrition and Physical Activity Laboratory, directed by Dr. Sisson, has a substantial track record of training students and providing opportunities in which undergraduate, professional, masters, and doctoral students engage in team-based and self-directed research. Among 24 trainees, 13 publications, in review and print, have been prepared and students have 7 1st author publications. Trainees have presented 15 poster and oral presentations at national and international conferences. Dr. Hildebrand also has a strong record of student mentorship and has successfully chaired thesis committees for fourteen graduate students. Of these, six students presented their research at the annual Oklahoma State University Research Symposium, with five being awarded 1st or 2nd place recognition. Student trainees have presented 9 poster presentations and have published abstracts and 2 have co-authored manuscripts. This grant award will enhance the research environment and promote successful research among student of various disciplines and training.

**2.G.3 Student Integration.** Students will be integrated throughout the project. Ethics, measurement, and intervention training programs have been described previously (Sections 2.C.2 and 2.C.7). Student researchers will be responsible for the logistics of the study and participant management, accurately collecting outcome measures, data management, implementation of Intervention materials, data interpretation, and dissemination. We aim to recruit 1 doctoral, 2 masters,

and 1 professional student for full-time work on this project. It is anticipated that other undergraduate, professional, and graduate students, supported by the Department of Nutritional Sciences, will contribute to the study. Students will have the opportunity to take ownership of small study segments and will present findings at conferences and disseminate work in peer-reviewed and lay platforms.

**2.G.4. Additional Scientific Exposures**. We will develop a monthly journal club at which articles relevant to nutrition and child health will be selected and discussed. We will coordinate an annual maternal and child health research colloquium and students will participate in a mentoring lunch in which the speaker shares personal comments about careers in science and the importance of the work in which they engage. Such events are critical in shaping malleable students and encouraging them to continue to pursue careers in science and technology.

**2.G.5. Expected Outcomes.** As noted in the timeline (Section 2.C.2 and Table 1), student experiences will be evaluated biannually using a short survey and qualitative interview. Discussion of student's Individual Development Plan will occur concurrently with these opportunities for feedback. Table 9 lists outcomes.

**2.G.6. Use of Results.** Results of Aim 4 will be used to guide academic program development to include students from under-represented colleges and universities in health research. Feedback will be provided to partners at each student-evaluation time-point, allowing for timely modification to most effectively enhance the quality of the research experience.

Table 9. Anticipated Student Outcomes

| Knowledge & Interest | Scientific Development |
|---|---|
| STEM-based careers<br>Health-research<br>Research ethics<br>Sensitivity of vulnerable populations<br>Logistical skills<br>Scientific rigor | Journal article presentations<br>Student-led publication<br>Student-led conference abstracts |

**2.G.7. Specific Timeline.** As described in Section 2.C.2 and Table 1, student experiences will be evaluated in March and October of each year. Reports describing these experiences and any modifications will be deliverable product following each evaluation.

**2.H. Limitations.** We have conservatively determined power, and plan to enroll a sufficient number of participants for Aims 1-3 to remain adequately powered even after attrition. Should recruitment be inadequate in the OKC area, we can expand to surrounding areas to recruit for a larger population. Should recruitment be limited in rural areas, we can expand to additional counties. Support from our CBPR partners will be essential for developing and maintaining these relationships throughout the study. Self-report measures are often associated with social-desirability bias. By combining self-report measures with trained observations, we strengthen the validity of the study. We will actively work to prevent protocol deviations with regular booster training and measurement and Intervention fidelity checks. Retraining can occur as needed.

**2.I. Hazardous materials**. This proposed project does not include the use of any hazardous materials for personnel or participants. Risk is not greater than daily living. Appendix K provides details on human subjects' protection.

**2.J. Feasibility.** This investigative research team complemented by our community, Extension, and social-service partnership is uniquely positioned and highly capable of successfully completing the proposed project in the timeline described (see biosketches and letters of support). Each of the investigators have expertise necessary to implement the research, outreach and extension, and student education components of the project. The team has been working collaboratively, with community partners, for over a year to develop this plan and ensure its feasibility. The involvement of key partners including the Department of Education, Department of Human Service, CACFP Sponsors, Extension Educators, and FCCH Providers ensure that project will be relevant, applicable, and achieve the goals of enhanced nutritional quality for young children.