

**Effectiveness of Differing Levels of Support for Family Mealtimes on Obesity  
Prevention Among Head Start Preschools**

**Trial #: NCT02487251**

**Protocols and Analytic Plans**

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## **Phase 1 Study Protocol**

In a factorial design with six intervention components reflecting supports for family mealtimes (e.g., meal delivery, cookware/dinnerware provision, nutrition education, etc.), individual participants were randomized to one of 64 experimental conditions. The 64 experimental conditions result from the crossing of six interventions, each of which had two conditions (present vs. not) and reflect all possible pairings of the intervention components including a condition with no intervention components. Feasibility was assessed via attendance/participation in intervention components. The intervention period was 8 weeks.

Families were recruited from two Head Start agencies serving a mix of rural and urban areas in mid-Michigan. Participants were recruited on-site at their children's Head Start programs during parent events or through informational packets that were sent home in children's backpacks. Parents expressing an interest in study participation were screened for eligibility. Written consent was obtained from all participants during a home visit. Families were assigned to study interventions through an automated random number generator.

Data collection teams were distinct from the intervention staff and were managed separately. Evaluators of study outcomes were blinded to the intervention components to which participants were assigned. After obtaining written informed consent and prior to starting the intervention, a data collector made a home visit to measure maternal and child weight and height and complete a series of questionnaires with the mother. Following the implementation of the intervention, a parallel post-intervention data collection visit was conducted.

## **Phase 2 Study Protocol**

Families were enrolled, consented and randomly assigned to the intervention or to usual care control group. Outcome measures were collected both pre- and post-intervention while data on dietary quality were also collected mid-intervention. Most data were collected in the home; however, with the onset of the global COVID-19 pandemic, data collection was moved to an online platform through which participants completed self-reported questionnaires. Because in-person data collection efforts were not possible, measurements of child height/weight and data on mealtime interactions were not collected for participants with data collection points falling after March 2020. Families received written and verbal information about the study and provided written informed consent. Data collectors and interventionists did not interact, and data collectors were blinded. Participants in the intervention condition received two meals per week for 12 weeks and they received a comprehensive set of cookware/dinnerware at the outset of the intervention delivery.

### **Phase 1 Analytic Plan**

The results of the six intervention components were identified by means of a factorial experiment involving the following factors: 1) Meal Delivery (provided vs. not); 2) Ingredient Delivery (provided vs. not); 3) Community Kitchen (provided vs. not); 4) Didactic Nutrition Education Classes (provided vs. not); 5) Cooking Lessons (provided vs. not); and 6) Cookware/Materials Provision (provided vs. not). Pre- to post-intervention change scores were calculated for each intervention condition. Using Cohen's  $d$  to assess effect sizes of pre-post changes for each primary and secondary outcome, results were categorized using the following a priori thresholds for interpretation and compared to the control condition: small ( $d \leq .30$ ), medium ( $d > .31$  and  $\leq .50$ ), and large ( $d \geq .80$ ). This emphasis was consistent with our objective of identifying a feasible, final set of bundled components. Then, paired t-tests were conducted to

examine pre- to post-intervention changes within the intervention combinations that included Meal Delivery and Cookware/Materials Provision (N = 65), identified as the two most feasible, and promising intervention components. Because sample sizes within each of the intervention combinations were small and because participation in all interventions except Meal Delivery, Ingredient Delivery and Cookware/Materials provisions was so negligible (described in the results), we elected to use combined samples in the paired t-tests analyses. Thus, the 65 participants received Meal Delivery and Cookware/Materials Provision but may have also received other interventions except for Ingredient Delivery. The rationale for this was that the extremely low participation in Community Kitchen, Nutrition Education, and Cooking Demonstrations would result in no intervention effects related specifically to these intervention components. As a caution, we also examined pre-post analyses with the small group of participants who only received Meal Delivery and Cookware/Materials Provision.

## **Phase 2 Analytic Plan**

Sample size was set at 125 per arm which, with 20% attrition, would enable detection of small to medium effect sizes of  $d = 0.40\text{SD}$  for continuous outcomes and 38% relative risk reduction for binary outcomes with a power of 80% and  $\alpha = .05$ . Baseline comparability of the intervention and control arms was assessed using two sample t-tests and chi-square. Baseline comparability of the full MOW cohort (intervention plus control) and full COM cohort (intervention plus control), baseline comparability of the MOW intervention and MOW control, as well as the COM intervention and COM control were assessed in the same manner. Mixed models were used to account for having repeated measures (pre and post). All analyses were done in SAS 9.4 and were adjusted for child's sex. Models of BMIz and dietary measures were also adjusted for season of data collection (summer vs. school year) as seasonal differences were

seen in the baseline data for these measures and seasonal differences in preschoolers' BMIZ have been reported in the literature (e.g., Lumeng et al., 2015). Additionally, models in the MOW sample adjusted for family structure and models in the COM sample adjusted for income-to-needs ratio, given baseline differences between the control and intervention groups within these cohorts. Analyses were based on the intention to treat principle such that all randomized participants were included in the analysis based on their randomized intervention group. Significance was assessed using a two-sided test at  $\alpha= 0.05$ .