Obesity Prevention in Head Start
NCT03672227
August 1, 2019

PROJECT NARRATIVE

A. Specific Aims. Obesity disproportionally affects low-income children.[1] Already by age 5, 20% of low-income children in the US are obese, a prevalence three times higher than among high-income children.[2] Obesity that emerges by this young age is persistent and contributes to sustained obesity and obesity-related chronic disease in adulthood.[3,4] Identifying effective approaches to prevent obesity among young, low-income children is a national priority.[5]

Family-style dining, in which children serve themselves food and drinks from communal dishes, is advocated as a strategy to prevent childhood obesity. It is theorized that family-style dining allows children to attend to their hunger and satiety, and consume only the amount of food they need to meet their energy needs.[6] The alternative, where adults direct children's intake, is theorized to interfere with children's ability to self-regulate their eating and cause excess weight gain.[7,8] Based on this theoretical model, the USDA's Child and Adult Care Food Program (CACFP), which provides meals to 4.2 million low-income children annually, and Head Start, the federally-funded preschool program that serves 42% of all preschool-aged children in poverty nationally, strongly encourage family-style dining.[9,10]

Contrary to current beliefs however, we posit that many low-income children are not able to self-regulate their eating and overeat when allowed to self-serve, leading to excess weight gain. Thus, family-style dining may increase, rather than decrease, obesity among low-income children. Basic behavioral and epidemiologic research suggests that chronic stress, which many low-income children experience, contributes to obesity-promoting appetite characteristics among children.[11-13] Laboratory-based experiments have demonstrated that appetite characteristics such as these lead to excessive consumption when children are allowed to self-serve.[14] Among low-income preschoolers, one-third to one-half of children consume calories in excess of Institute of Medicine recommendations[15] during family-style meals.[16,17] This excessive energy intake is driven by intake of meat and grains, while intake of nutrient-dense, lower calorie fruits and vegetables is far below recommendations.[18] Children's excessive and unbalanced eating during family-style dining is often noted by teachers, who are uncertain how limit these behaviors.[19]

Changing prompts to eating may be particularly important for modifying the dietary intake of young children who, unlike adolescents and adults, do not yet have the cognitive capacity to inhibit intake of highly palatable foods in favor of selecting food based on healthfulness.[21] Therefore, the objective of this Collaborative Research pilot study is to conduct T2 translational research among low-income preschool children by developing an easily-implemented alternative approach to family-style dining in Head Start called Mealtime Matters, where teachers receive focused training on preschooler nutrition, appropriate portion sizes for preschool children, and responsive feeding strategies that promote children's self-regulation of eating. The feasibility and impact of Mealtime Matters will be tested with 72 children from up to 7 Head Start classrooms in Adrian, Michigan. We hypothesize that Mealtime Matters will be feasible and acceptable to teachers. Further, by reducing prompts to over-consume and empowering teachers to direct children to serve appropriate portion sizes, we will: 1. Increase the proportion of children consuming within an acceptable range of the recommended kilocalories (kcal) during meals at Head Start[15] and 2. Increase the servings of fruits and vegetables children consume during meals at Head Start. Sustained engagement in these dietary behaviors can prevent excessive weight gain and obesity.[22]

The specific aims of this trial are:

Aim 1: Examine the effect of Mealtime Matters on children's dietary intake during meals at Head Start.
Aim 2: Examine the effect of Mealtime Matters on teacher/child mealtime interactions at Head Start.
Aim 3: Determine the feasibility and acceptability of Mealtime Matters among Head Start teachers.

B. Background and Significance. Family-style dining, where children serve themselves foods and drinks without interference by caregivers, is considered a best practice for obesity prevention. Allowing children to serve themselves is theorized to support self-regulation of eating – the ability to eat only when hungry and stop when full – as it is believed that children can recognize their own hunger, identify the appropriate amount of food or drink to address that hunger, and then serve themselves and consume only that amount. Experimental studies however demonstrate that some children consume more, not less, when allowed to self-serve.[23] Overeating during self-service is particularly pronounced among children who exhibit obesity-promoting appetite characteristics, such as high responsiveness to food cues.[14] The experience of chronic stress, such as stress of housing instability, food insecurity, and parents' marital disruption, is believed to contribute to these obesity-promoting appetite characteristics.[11-13] Therefore low-income children, many of whom have experienced chronic stress early in life, may be particularly at risk for overeating in self-serve environments.

Observational studies support the assertion that a meaningful proportion of low-income children overconsume when allowed to self-serve. The Institute of Medicine recommends that children in preschools participating in the Child and Adults Care Food program consume a median of 338 kilocalories (kcal) during lunch.[15] However Schwartz, et al.[15] observed that ~32% of children consumed >130% of the recommended energy during lunch at preschool. Dr. Bauer has extended this research and identified that excessive energy intake during family-style dining is driven by overconsumption of energy-dense meat and grains (e.g., bread, pasta, rice), while fruit and vegetable intake is far below recommendations. In a sample of 243 Head Start children participating in a recent trial led by Dr. Lumeng,[24] Dr. Bauer determined that children with high energy consumption during lunch at Head Start ate approximately 4 times as much meat and 3 times as much grains as compared to children whose energy intake was in the recommended range. Fruit and vegetable intake, however, did not differ between high consumers and recommended consumers. Overall, children consumed only 1/3 of recommended fruit and 1/4 of recommended vegetable intake. These dietary patterns place children at high risk for obesity and obesity-related chronic disease.[22]

Identifying effective approaches to limit and balance children's dietary intake is essential to addressing the epidemic levels of childhood obesity. Approaches that can be easily implemented in settings that serve low-income children are especially important given that childhood obesity is increasingly concentrated among low-income populations.[1] In the proposed efficacy study, we will pilot test the impact of a novel training, Mealtime Matters, in Head Start. In Mealtime Matters, teachers will receive training on nutritional needs of preschoolers, effective ways to promote healthy portion sizes for preschoolers, and responsive feeding approaches to limit pressured/coercive eating statements and promote children's self-regulation of eating. Based on the theoretical and empirical literature, we hypothesize that the modifications that this training makes on teacher behavior during meals will impact children's dietary intake. Many early childcare and education programs that serve low-income children provide children the majority of their recommended daily calories.[15] Improving children's dietary intake during these eating opportunities can make a large impact on their long-term growth and health. If, in a fully-powered effectiveness trial, Mealtime Matters is effective at improving children's nutrition and reducing obesity risk, dissemination of the practice to Head Start and other early childcare and education programs that serve low-income children can have a widespread impact on childhood obesity and obesity disparities nationwide.

C. Previous Related Work. Dr. Bauer is a behavioral epidemiologist who has extensive experience in research with observational cohorts to identify social and behavioral determinants of childhood obesity[32-47] and in the design, implementation, and evaluation of community-based pediatric obesity prevention interventions among low-income populations.[46,48-52] She recently completed a collaboration on a USDA-funded group randomized trial to test the impact of modifications to the federal School Breakfast Program on elementary school-aged children's dietary intake and obesity risk. In this trial, counter to hypotheses and recommended practice, children's self-service of breakfast in the classroom increased, rather than decreased, obesity risk over the school year.[53] Since joining the faculty of the University of Michigan School of Public Health as an Assistant Professor in 2015, she has been working with Dr. Lumeng, a developmental and behavioral pediatrician, and Dr. Kaciroti, a biostatistician, to expand her program of research to younger populations including low-income children engaged with Head Start. This collaboration led her to analyze dietary intake data collected from children participating in Dr. Lumeng's recent Head Start-based obesity prevention trial[24] and identify unbalanced eating by low-income children during family-style meals at Head Start (results presented in Background and Significance). These findings prompted the current application. Dr. Bauer has also built independent relationships with several Head Start agencies in Michigan over the past two years to

promote new observational and intervention research. She and Mr. Bull, Director of the Adrian Public School's Head Start program, have collaborated on the development of 5 research proposals over the past year. These efforts recently culminated in an award from the American Heart Association to examine maternal feeding practices in low-income families, recruitment for which is occurring in collaboration with Adrian Head Start. Finally, Dr. Martin is a clinical psychologist at the Pennington Biomedical Research Center with expertise in novel approaches to quantify energy intake in controlled and free-living conditions.[27-31,54-60] Dr. Martin developed and validated the Remote Food Photography Method. Dr. Bauer and Dr. Martin collaborate extensively through their service contributions to The Obesity Society and over the past year have increasingly been forming new research collaborations.

Dr. Tan and Dr. Brophy-Herb will additionally provide support for development of Mealtime Matters and analysis and interpretation of data on teacher/child mealtime interactions. Dr. Tan is an expert on preschool children's hunger and satiety signals and Dr. Brophy-Herb is an expert on early childhood education and training teachers to support children's nutritional and emotional needs.

D. Approach

D.1. Study overview.

We will first conduct two to three focus groups with Adrian Head Start teachers in spring 2018 to identify their knowledge and beliefs regarding feeding children. They will be compensated $20 each for participation along with lunch. The information gathered will be used to inform the Mealtime Matters curriculum. Afterwards, the Mealtime Matters training will be finalized.

Next, an information session will be scheduled with teachers to invite them to participate in the study. Then, once classrooms elect to participate, recruitment will occur of children in the study classrooms. Parents of these children will complete an informed consent form and a brief study survey. In-classroom data collection will then occur in fall 2018. Once baseline data collection is complete, teachers in classrooms will be randomized to receive the Mealtime Matters training in either fall 2018 or in spring 2019 (delayed treatment). Teachers trained in fall 2018 will also receive 2 booster training sessions to enhance protocol adherence. Follow-up data collection in classrooms and with teachers will occur during November/December 2018. Data processing, analysis, results dissemination, and development of an NIH R01 application to test Mealtime Matters in a fully-scaled efficacy trial will then occur.

D.2. Study population, recruitment, and enrollment criteria. To be eligible for Head Start, children must be 3 or 4 years old by the beginning of the academic year, therefore children will be between 3 and 5 years old during study participation. Children's families must also have a household income near or below the federal poverty line. Approximately half (58%) of children in the Adrian Public School's Head Start program are non-Hispanic white, 25% are Hispanic/Latino, 15% are African American, and 2% are of another race/ethnicity or are of mixed race/ethnicity. In 2015, 20% of children were obese and 16% were overweight.

Adrian Head Start teachers will be invited to participate in the spring 2018 focus groups, which will each last approximately one hour. Teachers will be invited to participate, sign a consent form, and will be compensated $20 each plus lunch for their time. An established focus group guide will be used for the session, which will be led by a trained staff member and audio-recorded. If there are changes in teacher staff before the training session, such as a new hire, or teachers switch rooms, we will have the option to enroll the new teacher in the classroom before data collection and/or training session occurs.

Seven classrooms at the Adrian Head Start will be invited to participate in the trial. Given the short length and focused content of the intervention, contamination between intervention conditions is of minimal concern, therefore study classrooms may be in the same school building. Each Head Start classroom can be led by 1 to 3 teachers. In the summer/fall of 2018, study staff will travel to Adrian to provide an informational session with all teachers who might participate. During this session, staff will review the consent form and answer any questions teachers might have. As stated on the consent form, they will be reassured again that their future employment does not depend on their participation, and that there will be no penalty at all for not participating if they do not wish to. Teachers interested in participating will then complete the consent form and brief teacher survey. Participating teachers will each receive $60 as compensation for their study involvement, $50 after the consent and survey process, and an addition $10 after the training and final survey measures are completed.

Parental consent for their children's participation in the trial will then be obtained for children enrolled in the study classrooms. To do so, staff members of Adrian who conduct required home visits to families before Head Start begins in the fall will hand out recruitment flyers to parents. Then, after school starts, an enrollment packet including a cover letter explaining the study and an informed consent form will be sent home to families. A few brief surveys for parents to complete will also be included in this packet. The informed consent will provide permission for children to participate in the study. Families can return the signed consent form and surveys in a sealed envelope to their child's Head Start classroom. A study phone number will be provided in the event that parents have any questions. The study will be approved by the University of Michigan Institutional Review Board and parents will be assured that participation is optional and will not affect eligibility for ongoing participation in and usual benefits of Head Start. Parents will be compensated a $15 gift card for the completion of the survey; this gift card will be mailed to them once we receive their completed survey.

A waiver for oral/written child assent will be requested as the research presents no more than minimal risk, waiver will not impact the rights and welfare of subjects, and assent is not practicable as the capabilities of children age 3-5 years old are limited. The children will not be asked to do anything different during their lunch and will be observed only. Children will get their height and weight measured by trained staff once at baseline and once at a follow up after the six weeks.

To be eligible for study participation, children must meet the following eligibility criteria: (1) the custodial and legal guardian is able to provide valid consent; and (2) the child is not a foster child, which leads to challenges with valid informed consent. Surveys in the study packet will let the study team know that a child might be ineligible. If a child is ineligible, no data will be collected from them despite the parent providing permission. Parents will still be compensated for returning the study packet.

Each Head Start classroom contains 17 children, therefore to achieve a sample size of 10 children per classroom or 60 children total, a consent rate of 59% is needed. In Co-I Lumeng's Head Start-based intervention that had similar eligibility criteria, 64% of families provided consent for their child to participate in the study.[24] Therefore, achieving a consent rate of 59% is highly feasible.

Children whose parents do not consent to study participation or who are not eligible for study participation may still be exposed to the intervention. Further, these children may be recorded in video recordings of mealtimes, however, no child-level data will be coded for these children. This information will be provided in the enrollment packet sent to parents describing that children's teachers may get additional nutrition training and the process of videotaping meals. Parents will then have the option to inform the study team that they do not want their child participating in these activities. If a parent informs the study team that they do not wish for their child to participate in these activities, then the child will be placed somewhere that is not in sight of the video camera, or in a different classroom for the 3 recorded lunches.

D.3. Mealtime Matters. Classrooms will receive extra training about children's nutrition and ways to promote children's healthy eating. The training will address the basics of preschooler nutrition, recommended portion sizes for preschoolers, and responsive feeding approaches. Responsive feeding is a child-centered approach to feeding where children are encouraged to be attuned to their hunger and satiety signals.[61] For example, if a child declines a portion of the meat/meat alternative or grains, the teacher may respond to them, "How does your tummy feel? Would you like a piece of bread to help your tummy feel full?" Teaching children such approaches for recognizing hunger and satiety have proven effective at improving children's self-regulation of eating.[62]

Teachers will participate in a 3-hour training led by nutrition students from the University of Michigan School of Public Health as well as 2, 1-hour booster sessions to enhance teachers' adherence to the protocol. During the initial training, teachers will be taught required portion sizes for each food type at each meal and simple tips for identifying serving sizes during meal service. Teachers will also receive "tip cards" to help identify recommended serving sizes. The trainers will lead activities to address teachers' common beliefs about child nutrition and feeding, and help teachers identify children's hunger and satiety cues as well as use responsive feeding approaches. The trainers will work with teachers to address their concerns to feeding children. Booster sessions will occur in weeks 2 and 3 of the intervention and will focus on addressing teachers' questions and concerns that may have arisen during the first 1-2 weeks of intervention implementation.

D.4. Data Collection Procedure. Data for the initial teacher focus groups will be collected via audio-recording. Trained study staff will collect data for the trial. Data collection staff will be bachelors master's level staff trained in public health and are distinct from the staff conducting teacher training. Data collection staff will be blinded to the condition assignments of classrooms. PI Bauer and the Project Manager, Brittany Ross, will train data collectors on implementing the data collection procedures with rigor. Baseline data collection will occur after teacher and child recruitment and before intervention implementation. Follow-up data collection will begin during the last 2 weeks of intervention implementation. Data will only be transferred via University of Michigan secure methods such as MBox or secure Internet email connection. REDCap will also be used to store data. REDCap is an electronic data capture (EDC) system that is secure, HIPAA compliant, and web-based. See the following website for more detail: https://www.michr.umich.edu/rdc/2016/8/3/redcap-software

E. Measures

E.1. Focus group questions can be found in the included focus group guide.

E.2. Children's dietary intake. Children's dietary intake will be measured at baseline and follow-up via the Remote Food Photography Method.[28,30] Data will be collected during 3 lunch periods. Although all feeding occasions are targeted by the intervention, we will observe changes in lunch intake because children are served the most foods and expected to have the highest energy intake at lunch, providing the greatest potential for variability in intake between conditions.

The Remote Food Photography Method captures images of children's cups and plates before they eat (pre-intake) and after they eat (post-intake) each serving. The method was developed and has been extensively tested by Dr. Martin, H. Raymond Allen, Ph.D., and colleagues. Staff will place a reference card next to each child's place setting and capture images pre- and post-consumption using a recording device such as an iPad, iPod, or GoPro that is not connected to the Internet. The images will then be saved and organized on a University of Michigan secure server. Once organized and stripped of any potential identifiable information, the images will be securely transferred to the Pennington Biomedical Research Center for data analysis. Head Start will provide nutritional information for every food and drink served during the observation period to match the images of children's food and drink with its exact energy and nutrient composition. The data analysis process relies on a computer program called the Food Photography Application©. The program allows the operator to identify a match for each food or drink from the recipes provided. The operator then uses the program to estimate portion size consumed by visually comparing participants' images to images of foods and drinks with a known portion size. This process relies on existing and validated methodology[28,30,63,64] and produces data including children's energy intake, intake of specific foods and food groups, and macronutrient and micronutrient intake.

During validation testing where children were given test meals and selected meals in a cafeteria, the Remote Food Photography Method differed in estimation of energy consumed by only 1.1±26.6 and 0.5±244.3 kcal, respectively, as compared to food weighing, a gold standard method of assessing intake.[26] The method has successful assessed children's dietary intake in Head Start[29] and it has been proven that trained research staff can validly photograph children's meals, even when children take multiple servings of a given food or drink.[29]

E.3. Teacher/Child Mealtime Interactions and Intervention Feasibility and Acceptability. The feasibility and acceptability of Mealtime Matters will be determined using two approaches: (1) video recordings of lunch at Head Start and (2) teacher completion of brief surveys. Video recordings of lunch will be conducted in classrooms pre and post-intervention. Video cameras will be placed unobtrusively in the classroom and teachers will not be informed of the purpose of the recordings, but they will be aware that the cameras are there to film lunchtime activities and nothing else. This mild concealment is necessary in order to accurately measure feasibility and acceptability of the intervention without bias; the use of this concealment is appropriate as the study poses no more than minimal risk to participants and does not adversely affect subjects' rights and welfare. Recordings will then be coded by trained study staff using coding schemes developed by Dr. Bauer, Dr. Lumeng, and Dr. Brophy-Herb to identify teacher/child mealtime interactions, and potential change in these interactions post training. Behaviors to be coded will include teachers' verbal and non-verbal cues to children regarding portion sizes, and teachers' responses to children's behavior. The behavioral coding will result in quantitative variables representing the presence or absence of specific behaviors and counts of specific behaviors. Videos will be coded by two staff members who have been trained to a reliability >.70.

Teachers will also complete brief surveys at baseline and follow-up. These surveys will assess teachers' feeding practices and at follow-up and elicit information including teachers' overall satisfaction with the intervention and intervention training, challenges to intervention implementation, perceived child responses to the intervention, and unmet needs.

E.4. Covariates. We will collect the following covariate data: (1) children's weight and height, measured using standardized protocols,[66] to calculate body mass index (BMI), (2) child birthdate, (3) child sex, (4) child race/ethnicity, (5) maternal education, (6) family income-to-needs ratio, and (7) child eating behavior.

E.5. Statistical analysis and sample size. After completion of the study, the data will be unblinded and analysis will be performed following the plan described below. Prior to conducting analyses, we will run descriptive statistics and transform skewed outcome variables as necessary. Analyses will be based on the intention to treat principle where all the randomized participants, including children who did not complete follow-up data collection, will be included in the analysis based on their randomized intervention group.

To examine the effect of Mealtime Matters on children's dietary intake, baseline comparability of the two groups will be assessed using t-tests for continuous sociodemographic variables and chi-square tests for categorical sociodemographic variables. Then we will employ logistic regression models using general estimating equation techniques accounting for classroom clustering of behavior to identify associations between study condition and binary outcomes (e.g., proportion of children consuming > 130% of recommended kcals). Multi-level linear regression models accounting for within-classroom clustering will be used to examine associations between study condition and continuous outcomes (e.g., servings of fruits and vegetables consumed. Analyses will be conducted unadjusted and adjusted for baseline characteristics including child age, sex, race/ethnicity, BMI, and baseline levels of the outcome. Similar analyses will be used to examine the impact of the intervention on teacher/child mealtime interactions.

To determine the feasibility and acceptability of Mealtime Matters among Head Start teachers (**Aim 3**), we will use univariate statistics to describe teachers' quantitative responses to the survey and qualitative responses will be summarized by trained study staff to identify impactful and consistent themes. Teachers' quantitatively-coded behavior from the video recordings will also be described using univariate statistics. The research team will review the distributions of behaviors and responses from these sources and develop a summary report regarding the acceptability and feasibility of the intervention including reflections on areas for continued improvement.

We are interested in estimating effect sizes of the intervention for a future fully-powered efficacy trial. We do not anticipate that given our sample size, we will be able to detect significant differences between conditions at $p<.05$. However, assuming an intraclass correlation of 0.05 and 3 classrooms/condition with 10 students each, we will be able to detect an effect size of 0.79SD at $p<.05$.

E.6. Potential Challenges and Alternative Approaches. Collaborating with Head Start necessitates working within their academic year and being considerate of challenges facing the organization. Although we have a well-established relationship with Head Start, there is a chance that there will be too many competing priorities to begin recruitment. We have developed our timeline such that recruitment can begin in September 2018 and we can still complete the study protocol before the end of the academic year. If recruitment is not possible before September 2018, we will begin the trial in 2019 upon the start of the new school year. We also recognize that having research staff in Head Start classrooms may be distracting for children. To minimize this concern, research staff will conduct a run-in day of food photography during the baseline and follow-up periods. We will also run a quick pilot testing before data collection in order to refine the Remote Food Photography protocol; no identifying information or identifying pictures will be collected at this time. The presence of research staff is also equal across conditions, minimizing concerns of bias.

F. Study timeline

Feb 2018: The Project Manager will develop and submit the study's IRB application.
April/May 2018: Focus group session with teachers.
Aug/Sep 2018: Up to seven classrooms will be identified to participate in the study, teachers and children in these classrooms will be enrolled in the study. The Mealtime Matters training will be finalized.

Oct 2018:	Baseline data will be collected. Processing will begin on dietary intake data collected by the Remote Food Photography Method. Classrooms will be randomized and training implemented
Dec 2018:	Follow-up data collection. Teachers will complete teacher surveys after completion of the intervention.
January 2019:	All data will be processed and cleaned.
February 2019:	Data analysis will be conducted.
Jan/Feb 2019:	The study team will develop a presentation for Adrian Public School's Head Start program to communicate study findings. A peer-reviewed manuscript and an NIH R01 application to be submitted in February 2019 will be developed.

G. References

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