Intervening in Food Insecurity to Reduce and Mitigate (InFoRM) Childhood Obesity

National Clinical Trial (NCT) Identified Number: NCT05586269

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Sponsor: Boston Children's Hospital

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Description: Study protocol and analysis plan

STUDY PROTOCOL

BACKGROUND

"Food is medicine" focuses on the integration of food and nutrition interventions, also referred to as nutrition security, in the healthcare system. Medically tailored meal (MTM) programs have been shown to reduce food insecurity, improve dietary quality, and decrease healthcare utilization for adults with chronic illnesses.[41,2] This evidence has paved the way for Medicaid in some states, including MA, CA, NY, and MI, to reimburse MTMs and similar nutrition support for eligible adults. Meal kits with step-by-step home preparation instructions, which further provide nutrition education alongside healthy food, are an innovative adaptation to MTMs. EatWell, a Boston-based company, provides healthy, culturally tailored meal kits with fresh ingredients and easy-to-follow recipes to food-insecure populations. Despite the evidence in adults, there is a *major knowledge gap* and a lack of evidence to support nutrition security interventions such as meal kits to treat obesity and nutritional disorders in children and families. But the potential is substantial since childhood is an important period where health behaviors such as diet can set the stage for cardiometabolic health over the lifespan.[3,4]

SPECIFIC AIM

Pilot a 6-week meal kit delivery program using a randomized, cross-over trial design in 30 families with children (6-11 years old) with food insecurity and obesity.

DESIGN

Study Design & Population: Drawing from children who receive primary care at Boston Children's at Martha Eliot Health Center (Martha Eliot), we will recruit dyads (child + primary caregiver/parent). Martha Eliot serves families who are predominantly publicly insured (~75%) and self-identify as Hispanic or Latinx (~70%). Prior to the pandemic, ~12% of families at Martha Eliot reported food insecurity. Children with BMI $\geq 95^{th}$ percentile and a positive screen for food insecurity screened routinely on the 2-item Hunger Vital Sign™[5] will be eligible. We will use a randomized, cross-over trial study design. We have chosen this design due to concern about the ethics of withholding a potentially beneficial intervention to a vulnerable population of families with unmet social needs. We have also chosen this design because it provides a randomized control trial method.

Inclusion Criteria: Dyads (also referred to as "participants") including children who are 1) 6 to 11 years old 2) with a BMI $\geq 95^{th}$ percentile 3) screened positive on the 2-item Hunger Vital Sign™ 4) in a household of ≤ 5 people, 5) living with an English and/or Spanish-speaking caregiver and 6) living within the EatWell delivery map boundaries in the greater Boston area.

Exclusion Criteria: Participants (either child or parent) with a history of 1) food allergies or intolerance to dairy, gluten, soy, or any potential component of the meal kit; 2) malabsorptive intestinal disease (e.g., Crohn's disease, celiac disease); 4) type 1 or 2 diabetes; 5) solid tumor or bone marrow transplant; or 6) enteral tube dependence.

Intervention: EatWell meal kits will be delivered once weekly to households for 6 weeks. Healthy meal kits are developed by a trained chef and registered dietician. Each household will receive one meal kit per week.

Randomization: Participants will be randomized to one of two intervention sequences:

A) Meal kit intervention without delay followed by newsletter + pantry referral (standard of care)
B) Newsletter + pantry referral followed by meal kit intervention after a delay of 8 weeks

The printed newsletter lists additional local food assistance resources.

Sampling/Power: A pilot study is defined as "a small-scale test of the methods and procedures to be used on a larger scale."[6] We will assess the feasibility of an intervention to be refined for a larger-scale RCT. We will also assess the short-term impact of the pilot intervention. The planned sample of 30 dyads (a total of 30 children + 30 caregivers) is based on practical considerations, including participant flow, budgetary constraints, and the number needed to reasonably evaluate the feasibility of the intervention.

Study Visits: We have outlined the three study visits (**Table 1**), which will initially collect baseline demographic, medical and dietary history, provide questionnaires, and measure weight and height. Follow-up visits will be

conducted between Periods 1 and 2 (6 weeks), and then after Period 2 (14 weeks). Follow-up visits will include dietary assessments and questionnaires and measure the children's weight and height.

Table 1. Outline of study visits and measures collected

Study Visit	Measures
V1, in-person: Participants will meet with the study physician and research assistant to review eligibility criteria and obtain informed consent (including assent from eligible participants).	• Baseline demographics: age, sex, insurance type, and race and ethnicity. • Medical history: to assess for underlying gastrointestinal, endocrinologic, cardiometabolic, allergic conditions, and current and past medication history. • Dietary assessment • Questionnaires • Anthropometrics: weight, height, and calculated BMI for each child
V2, in-person: Participants will meet with the research assistant.	• Dietary assessment • Questionnaires • Anthropometrics
V3, in-person: Participants will meet with the study physician and research assistant.	• Dietary assessment • Questionnaires • Anthropometrics

Study Outcomes: The primary, intention-to-treat analysis will examine the feasibility of the meal kit delivery intervention. We will assess primary outcomes of feasibility of recruitment, randomization, retention, adherence, protocol, and assessments.[7] Primary outcomes will be assessed throughout the study. We will assess secondary outcomes of the intervention's short-term impact, which will include questionnaires on food insecurity and anthropometrics. Secondary outcomes will be assessed at Visits 1-3. We will additionally include the assessments we plan to include in a future RCT, including diet quality, mealtime behaviors, and perceived stress.

Analysis Plan: Consistent with the goal of pilot studies, our analysis will be mainly descriptive.[8] However, we will collect secondary outcomes including severity of household food insecurity and child BMI. We will collect and describe dietary quality and mealtime behaviors, among other assessments, and EHR data. We will present secondary outcomes as means (with standard deviations) or proportions.

ADVERSE EVENT CRITERIA AND REPORTING PROCEDURES

This proposal seeks to pilot and evaluate implementation of a nutrition security intervention using weekly meal kit delivery in food-insecure families with children 6 to 11 years old with obesity. This intervention will be tested at Boston Children's at Martha Eliot Health Center. This proposed study will leverage the existing partnership with EatWell meal kits. EatWell meal kits are prepared at Commonwealth Kitchen in Boston, MA, which adheres to a rigorous food safety program and complies with National Restaurant Association ServeSafe requirements and FDA requirements, and other applicable regulations, in addition to being regularly inspected by the City of Boston. The meal kits occasionally contain gluten and diary, but do not contain tree nuts or peanuts, although they are manufactured in a shared use facility and the product may contain trace amounts of Milk, Eggs, Fish, Shellfish, Tree Nuts, Peanuts, Wheat, and Soy. Any patients with food allergies or intolerance to potential components of EatWell meal kits will be excluded from participation to avoid any risk of allergic reaction to any of the meals. Therefore, this study poses minimal risk to participants.

We will obtain approval from the Boston Children's Institutional Review Board (IRB) for each of the aims, and we will participate in their standard annual continuing review process. We will also require that all staff and investigators working on this project complete human subjects research training. We will establish a data safety and monitoring board (DSMB) that will meet every 4 months. We will include experienced clinical trial researchers who are independent experts outside of our research team, in addition to Dr. Wu, Dr. Duggan and Dr. Liu. The Principal Investigator, Dr. Wu, will be responsible for monitoring the safety of this study. Dr. Wu will promptly report adverse events and other study-related information to the IRB. Clinical staff at the health center will be directed to report any suspected events related to this research to Dr. Wu. Protocol deviations will be reported to the IRB, along with an annual status report as per IRB guidelines. Adverse events are not anticipated for this study given the low-risk nature of the proposal.

DATA MANAGEMENT METHODS

All study data will be stored on password-protected computers and identified with study IDs. Analytic data files will contain no identifying information. No study report will allow identification of individual participants. Individual patient data collected as part of the intervention surveys or interviews will be kept confidential. Access to identifiable information will be strictly limited to study personnel who require such information to complete the work (e.g., study physician and research coordinator). Whenever possible, printed materials that contain identifying information (e.g. thank you letters) will contain no information revealing diagnoses, treatment, or other clinical information. All study staff will have CITI certifications and will be trained in IRB protocols.

STATISTICAL POWER AND SAMPLE CONSIDERATIONS

STATISTICAL DESIGN

We will use a randomized, cross-over trial study design. We also chose this design because it provided a randomized control trial method. Participants will be individually randomized to one of two intervention sequences:

A) Meal kit intervention without delay followed by newsletter + pantry referral (standard of care)
B) Newsletter + pantry referral followed by meal kit intervention after a delay of 8 weeks

Each group will receive 6 weeks of meal kit delivery and will be observed in the study for a total of 14 weeks.

POWER

The goal of our pilot study is to assess the feasibility, short-term impact, and implementation of a pilot nutrition security intervention using a meal kit delivery program. Results will be used to refine the intervention for a larger scale trial. The sample of 30 families is based on practical considerations, including participant flow, budgetary constraints, and the number needed to reasonably evaluate feasibility goals.

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