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SHORT COMMUNICATION

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Satisfaction with a meal kit delivery program and feasibility of a phase I trial in the intervening in food insecurity to reduce and mitigate (InFoRM) childhood obesity study

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Summary

Background: Food and nutrition security interventions have been demonstrated to optimize health, prevent and treat chronic diseases among adult populations. Despite the increasing prevalence and intersection of food insecurity and childhood obesity in the United States, there are few food and nutrition security interventions targeted to children and families.

Objectives: The primary purpose of this phase I randomized, crossover trial was to assess the safety, acceptability and satisfaction of a meal kit delivery program among children with obesity living in households with food insecurity. Secondarily, we assessed the feasibility of our study design, recruitment and retention to inform future larger scale trials.

Methods: We delivered 6 weeks of healthy meal kits, which included fresh pre-portioned ingredients and simple picture-based recipes (two recipes/week) in English or Spanish to prepare one-pot, under 30-min meals (after preparation ~10 servings/week).

Results: Caregivers received and prepared the meal kits and reported overall satisfaction with the meal kit delivery program.

Conclusion: A meal kit delivery intervention for children with obesity and food insecurity is acceptable and a phase I randomized, crossover trial is feasible.

KEYWORDS
childhood obesity, clinical trials, food insecurity, nutrition

1 | BACKGROUND

Childhood obesity, defined as body mass index (BMI) ≥95th percentile for age and sex, is prevalent in over one in five (26.2%) Hispanic children and is increasing.[1–3] Food security is a critical social determinant of health,[4] and more specifically, nutrition security refers to the access and availability of foods that promote health, prevent and treat disease.[5] Food insecurity has been associated with increasing weight and BMI in longitudinal studies of adults.[6] Nutrition security interventions, such as medically tailored meals, have been shown to reduce food insecurity, improve dietary quality and decrease healthcare utilization for adults with chronic illnesses.[7,8]

In contrast, the association between food insecurity and rising obesity prevalence in children remains understudied. A study among 794 children from low-income households in a pediatric weight management program observed that food insecurity was associated with a

less favourable weight trajectory among children with obesity,[9] which suggests that food insecurity may present barriers to optimizing pediatric weight management. The evidence for nutrition security interventions among children is lacking, and there are few randomized control trials to support the implementation of nutrition security interventions in the healthcare setting.

Applying the Obesity-Related Behavioral Intervention Trials (ORBIT) model, a phase I trial is intended to define basic elements of an intervention and refine the intervention prior to phase II testing, where the goal is to produce a clinically significant signal.[10] The primary purpose of the InFoRM phase I study is to assess the basic elements of the intervention, including safety, acceptability and satisfaction, of meal kit delivery for children with obesity and food insecurity. The secondary purpose is to assess feasibility of a randomized, crossover trial design, recruitment and retention for future study phases.

2 | METHODS

2.1 | Study design, setting and participants

We recruited primary care patients at Boston Children's at Martha Eliot Health Center in Boston, MA (February–March 2023). The target recruitment sample of 30 dyads was based on the number needed to reasonably evaluate satisfaction and feasibility in a phase I trial. Children met the following inclusion criteria: (1) 6–11.9 years old at baseline, (2) BMI ≥95th percentile, (3) positive screen on the 2-item Hunger Vital Sign™,[11] (4) household of ≤5 people, (5) English and/or Spanish-speaking caregiver and (6) address in the greater Boston area and within the EatWell delivery boundaries (~10 miles from the health centre). We chose this age range based on scientific rationale (e.g., obesity prevalence is stratified by age groups 2–5 years, 6–11 years and 12 and above in longitudinal assessments)[1] and the suitability of the intervention for school-aged children. We excluded children 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., celiac or inflammatory bowel disease); (3) type 1 or 2 diabetes; (4) solid tumour or bone marrow transplant or (5) enteral tube dependence. Children with any of the above conditions may have required special diets that the meal kits could not have accommodated.

Using the electronic health record, we identified potentially eligible participants, by age and BMI, scheduled for an upcoming in-person well-child or urgent care clinic visit. The study team approached participants to screen for eligibility using a written questionnaire, then consented eligible child–caregiver dyads. The study statistician generated a randomization list using block randomization (block size of either 4 or 6) to one of two intervention sequences: (A) meal kit intervention followed by newsletter with food assistance resources and food pantry referral or (B) newsletter and pantry referral (standard of care) followed by meal kit intervention (Supplement). All procedures were approved by the Boston Children's Hospital Institutional Review Board. The study was registered at ClinicalTrials.gov (NCT05586269).

2.2 | Intervention

EatWell Meal Kits (Boston, MA) are developed by a trained chef and certified health coach (Supplement).[12] Families received 6 weeks of free meal kit delivery. Each meal kit included fresh ingredients and picture-based recipes (two recipes/week) in English or Spanish to prepare one-pot, under 30-min meals (after preparation ~10 servings/week).

2.3 | Data collection

We conducted a total of three study visits (February–June 2023) at Martha Eliot Health Center. During the baseline visit, we collected the following information and assessments: demographics, dietary history,[13] caregiver perceived stress[14] and degree of household food security.[15] At each study visit, anthropometrics were collected by trained clinical or research assistants using standard procedures, including a stadiometer for standing height and Welch Allyn Scale-Tronix® scale for weight. Timeline and details about the follow-up visits and assessments conducted during each visit are outlined in the study schema (Supplement). Data were recorded in a secure digital platform (Research Electronic Data Capture).[16]

2.4 | Analysis

The cohort's baseline demographics are described using means and standard deviations or proportions. Our primary outcomes included safety, acceptability and satisfaction. We assessed secondary outcomes of study feasibility, including recruitment, randomization and retention. We conducted all analyses using R Studio, version 4.1.0 (Posit Software).

3 | RESULTS

Of 91 children screened for eligibility, we approached 47 children, of which 35 children met inclusion criteria (Figure 1). We recruited 30 child–caregiver dyads in 1 month (February to March 2023) and randomized dyads to: (A) immediate meal kit delivery or (B) delayed delivery. There were 22 (73%) dyads who completed the study (determined by completion of the satisfaction questionnaire in the final visit) and 19 (63%) dyads who completed all in-person visits (including anthropometrics) and surveys. No safety events or discontinuations occurred.

Among the 30 dyads in our baseline cohort, there were 30 children (one pair of siblings) and 29 caregivers (Table 1). Overall,

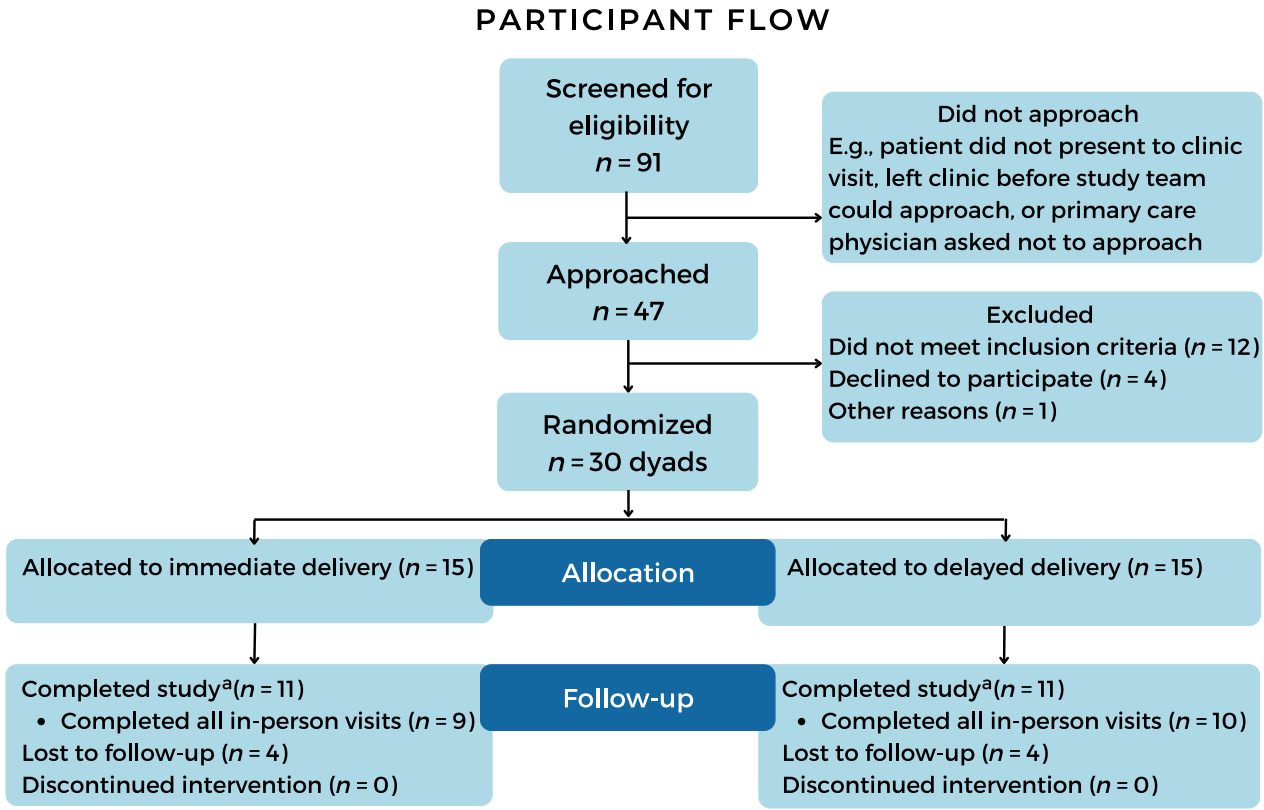

FIGURE 1 Participant flowchart. [a]Completion of satisfaction questionnaire in visit 3.

50 (85%) participants identified as Hispanic, 13 (43%) children identified as female and 25 (89%) caregivers were mothers.

We collected satisfaction data from 22 (73%) dyads. Of those who responded, 21 (95%) caregivers reported overall satisfaction with the meal kit delivery program. One meal kit per week included two recipes, and participants received a total of 12 recipes during the intervention period. Nearly all participants (21, 95.5%) received all meal kits and prepared at least one recipe; among those that prepared the recipes, some reported that they prepared 1–2 recipes (6, 28.6%), 3–6 recipes (10, 47.6%) or 7–12 recipes (5, 23.8%). Thirteen (62%) caregivers were satisfied with the cultural appropriateness of the meals (i.e., meals met taste preferences of their culture or country). Twenty-one (95%) children tasted/ate the food from the meal kit and 19 (86%) children reported liking the food. Eight (38%) children helped prepare a meal.

While we measured additional, exploratory outcomes to ensure assessments would be feasible in future studies (Supplement), we were not powered to detect changes in our phase I study. These results are beyond the scope of this short communication and are not included.

4 | DISCUSSION

In our study, we found that a meal kit delivery intervention was safe and acceptable for children with obesity and in households reporting food insecurity. Nearly every household received all 6 weeks of meal kit deliveries, most caregivers reported overall satisfaction with the program, and most children liked the meals they ate/tasted. Regarding study feasibility, we achieved target sample recruitment in 1 month and 73% of participants completed the randomized, crossover trial.

This phase I randomized control trial is the first meal kit delivery intervention focused on children, aged 6–11.9 years, with obesity and living in households with food insecurity. In a non-randomized trial, Food FARMacia piloted a mobile food pantry intervention among families ($N = 50$) with children <6 years old in New York City, USA; the food security intervention, recruitment and retention were feasible, with a similar attendance rate >70% for most participants.[17] A meal kit program pilot ($N = 36$) in Florida, USA, for African-American families with low incomes found the program was implementable and acceptable; meal kits were required to be picked up and utilization ranged from 80.6% to 97.2%.[18] In our cohort, 95% of families prepared at least one meal kit recipe.

Our study findings expand the limited research on meal kit delivery; additionally, meal kits are acceptable among households with food insecurity and tasted and liked by children with obesity. Further, meal kits were generally considered culturally appropriate. As data on food and nutrition security interventions emerge, comprehensive evaluations starting with phase I trials will assist the development of patient-centred and equitable interventions, particularly for vulnerable populations.

TABLE 1 Baseline characteristics of caregiver–child dyads.

Characteristics	Mean (SD) or *N* (%)
Children ($n = 30$)	
Age, years	8.7 (1.8)
Female (%)	13 (43.3%)
Hispanic ethnicity[a]	26 (89.7%)
Race[b,c]	
American Indian	2 (6.9%)
Black	13 (44.8%)
Native Hawaiian or Pacific Islander	1 (3.4%)
White	7 (24.1%)
Another	4 (13.8%)
Prefer not to answer	3 (10.3%)
BMI	
BMI, kg/m^2	25.95 (4.62)
BMI extended *z*-score	2.3 (0.9)
BMIp$_{95}$	120.5 (22.4)
Caregivers ($n = 29$)	
Age, years	39.7 (6.4)
Female (%)	25 (89.3%)
Hispanic ethnicity[a]	24 (85.7%)
Race[b,c]	
American Indian	2 (7.1%)
Black	11 (39.3%)
Native Hawaiian or Pacific Islander	1 (3.6%)
White	6 (21.4%)
Another	4 (14.3%)
Prefer not to answer	5 (17.9%)
BMI, kg/m^2	31.23 (6.16)
Spanish language preferred	21 (72.4%)
Household food security status[c]	
High	0 (0%)
Marginal	1 (3.6%)
Low	19 (67.9%)
Very low	8 (28.6%)
Annual household income[c]	
<$20 000	17 (60.7%)
$20 000 < $70 000	5 (17.9%)
>$70 000	2 (7.1%)
Don't know or prefer not to answer	4 (14.3%)

Note: Data presented as mean (SD) or *N* (%).
Abbreviation: BMI, body mass index.
[a]Participants response to 'Are you/your child of Hispanic, Latino/a, Latinx or Spanish origin?'.
[b]Participants prompted to check all that apply.
[c]Missing data ($n = 1$).

A limitation of this study was the small sample size, which was recruited from an urban, pediatric primary care clinic. A phase I design study is not powered to detect change in behavioural risk factors or clinical outcomes. As our intervention included ~2 meals/week for 6 weeks, future studies warrant an increased intervention dose and duration to test the impact on dietary quality, household food security and BMI.

In conclusion, our study demonstrates that families with food insecurity and a child with obesity were satisfied with a meal kit delivery intervention. In addition, the study's randomized, crossover design, recruitment and retention were feasible. Ongoing research includes an implementation evaluation and qualitative interviews among caregivers to understand the barriers and facilitators of the intervention, which will refine the intervention for a phase II trial.

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CONFLICT OF INTEREST STATEMENT

No conflict of interest was declared.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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