Reducing Health Disparities Through an Adaptive Healthy Eating Program for Underserved Infants in a Home Visiting Program (Healthy Eating for My Infant; HEMI)

NCT04977947

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Statistical Analyses and Power

1. Outcome assessment and definitions

Our primary outcome for this study is infant Body Mass Index (BMI).

Outcome	Assessed when?	Metric(s)	Continuous or categorical	Maximal range	Hypothesized results
Infant anthropometry	Baseline, post-treatment	Percent of infants with BMI $\geq$ 85th percentile, by treatment group	Categorical	0% to +100%	Intervention < Control
Infant anthropometry	Baseline, post-treatment	Pre- to post-study change in BMI percentile, by treatment group	Continuous	-99% to +99%	Intervention < Control

Our secondary outcomes are infant diet and intervention acceptability

Outcome	Assessed when?	Metric(s)	Continuous or categorical	Maximal range	Hypothesized results
Infant diet diversity	Baseline, post-treatment	Pre- to post-study change in number of food groups provided in previous day, by treatment group	Continuous	-7 to 7	Intervention > Control
Infant diet quality	Baseline, post-treatment	% kcal from fat Servings vegetables+ fruits	Continuous	0 or greater	Intervention < Control Intervention > Control
Treatment adherence	Throughout treatment	Proportion of treatment sessions completed by participants in the treatment condition	Continuous	0 to 6	At least 5 of 6 sessions completed
Treatment fidelity	25% of intervention visits	Provision of intervention components as specified in module	Continuous	Varies relative to module goals	<5% of module components not covered
Maternal feedback	Post-treatment	Proportion of mothers indicating positive view of program	Categorical	0% to 100%	>90% indicate positive view
Peer Counselor feedback	Post-treatment	Qualitative coding of themes	Qualitative	n/a	n/a

2. Analyses

For Aim 1, GLA data analysis will be conducted in real-time by the participants during the session. Facilitated by Co-I Vaughn, participants will reach consensus on overall themes and action items, such as the content to be included in each treatment module. Demographic information of stakeholders will be summarized using descriptive statistics.

For Aim 2, descriptive statistics of the study population will be summarized. Treatment adherence will be assessed as the number of treatment visits completed within 1 week of the monthly time window. Missed visits will trigger an analysis of the situation and attempted communication with the mother to gather additional information about why study visits were not completed. Treatment fidelity will be assessed using coding of audiotapes for 25% of the visits. The maternal feedback on the program will be conducted at the post-treatment visit, and qualitative/open ended questions will be coded and analyzed for themes for improvement of the intervention. Peer counselor feedback on the program will be assessed through interviews after all treatment sessions have been delivered. Responses to open-ended questions will be analyzed for themes and also used to further modify the intervention.

For all Aim 2 effectiveness outcome variables, analyses will be conducted using two-sample t-tests or non-parametric Wilcoxon rank sum tests to evaluate between-group differences for continuous variables, and Fisher's exact tests of contingency tables for categorical variables. Prior to conducting analyses, distributions of outcome variables will be assessed to determine the appropriate modeling approaches. All primary analyses will be conducted using intention to treat (ITT) analysis, including all individuals who were enrolled. Given the small sample size, imbalances may arise between the randomized study groups. If groups are unbalanced at baseline, these baseline variables will be included in adjusted general linear model or logistic regression models, depending on the outcome, with adjusted differences in outcomes estimated by intervention group. P-values < 0.05 will be considered significant. Every attempt will be made to collect demographic and psychosocial covariate measures. However in the event of missing covariate data, we will use multiple imputation techniques to handle missing data in the statistical models.

As sensitivity analyses, efficacy analyses will be conducted analyzing individuals participating in at least half of the study visits; Analyses will also be conducted adjusting for the number of visits completed, to determine the impact of intervention completion on the Aim 2 outcomes.

3. Statistical Power, Aim 2

Primary outcomes: Data from a previous study in the *ECS* population identified that 31% of infants had BMI ≥ 85th percentile at age 9 months. Assuming this represents the *ECS* control population for this pilot study, 15 infants per group would provide 42% power to detect the reduction of this rate to 0% by 9 months in the intervention group, at $p<0.05$. A similar power (43%) was obtained when modeling continuous change in BMI percentile between 3 and 9 months of age, which had a mean (SD) change of 19.6 (29.3) percentile points, assuming the intervention group would achieve no mean change in BMI percentile and equal variance with the control group. Thus, this study will be underpowered to identify significant changes due to the intervention, but will enable estimation of the effect size to power larger studies.

Secondary outcomes: Previous observational data from a cohort of Cincinnati infants living in an urban environment found that the number of food groups fed increased by an average of 3.4 ± 1.4 food groups between ages 3-9 months. (Woo 2015) Assuming equal variance between the intervention and control groups, and 15 infants per group, this pilot study would have 75% power to detect a 1 SD (1.4 food group) difference in the increase of food groups between intervention groups at $p < 0.05$. We thus anticipate that this pilot intervention will also be underpowered to evaluate changes in our secondary outcomes of infant diet, but will be informative with regard to the anticipated effect size and resulting sample size required in a larger trial.