

Official Title: Evaluating the Effectiveness of a Food is Medicine Community Health Worker Program for Pregnant Women: Addressing Social Needs and Improving Health Outcomes

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Statistical Analysis Plan

Aim 1: To assess the feasibility of the Women's Health Delaware Food Farmacy and refine the program as needed

Descriptive statistics will be used to summarize the feasibility (i.e., acceptability, demand, and implementation; Bowen et al., 2009) of the Women's Health Delaware Food Farmacy. The feasibility will be assessed using metrics such as: (1) program satisfaction; (2) study recruitment, enrollment, and retention; (3) meals provided; (4) food consumption; (5) Community Health Worker interactions; and (6) educational videos watched. In addition, open-ended questions related to program satisfaction will be analyzed using thematic analysis.

Aim 2: To determine the prevalence of and change in social needs

Descriptive statistics will be run to summarize the number of social needs identified at baseline and postpartum and the social needs resolved and unresolved through resource referrals among patients in both the Women's Health Delaware Food Farmacy and the usual standard of care. Social needs will be identified by administering ChristianaCare's Social Determinants of Health Screener (adapted from the Accountable Health Communities Health-Related Social Needs Screening Tool; the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences Screening Tool; and the Health Leads Social Needs Screening Toolkit) and sending resource referrals on patients' behalf to support their needs, both of which are standard of care. General/generalized linear models will be run to compare changes in social needs at baseline to postpartum among all participants.

Aim 3: To evaluate the effectiveness of the Women's Health Delaware Food Farmacy on maternal and child health, healthcare utilization, and clinical event outcomes as well as patient-reported outcomes compared to the usual standard of care

A series of general/generalized linear models will be run to compare patients in the Women's Health Delaware Food Farmacy compared to the usual standard of care on a number of maternal and child health outcomes (e.g., gestational age and preeclampsia), healthcare utilization (e.g., Neonatal Intensive Care Unit admission and maternal length of stay), and clinical events (e.g., cesarean delivery and fetal death) as well as patient-reported outcomes (e.g., food security, dietary intake, quality of life, and cost-related medication underuse). Models will include indicators for randomization blocks and will also control for baseline estimates, when applicable, and relevant covariates will be considered to improve the precision of estimation of effects. In order to adjust for multiple comparisons, the Benjamini-Hochberg procedure will be used for controlling the false discovery rate (Benjamini & Hochberg, 1995). In addition, the intent-to-treat and treatment on the treated impacts will be calculated (Imbens & Angrist, 1994).

References

- Benjamini, Y., & Hochberg, Y. (1995). Controlling the false discovery rate: A practical and powerful approach to multiple testing. *Journal of the Royal Statistical Society: Series B (Methodological)*, 57(1), 289–300. <https://doi.org/10.1111/j.2517-6161.1995.tb02031.x>
- Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., Kaplan, C. P., Squiers, L., Fabrizio, C., & Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine*, 36(5), 452–457. <https://doi.org/10.1016/j.amepre.2009.02.002>
- Imbens, G. W., & Angrist, J. D. (1994). Identification and estimation of local average treatment effects. *Econometrica*, 62(2), 467–475. <https://doi.org/10.2307/2951620>