

ClinicalTrials.gov Title Page

Document: Statistical Analysis Plan

Official Study Title: The Effect of Supplemental Nutrition Assistance Program-Education on the Dietary Intake of Low-income Indiana Participants

NCT #: NCT03436784

Document Date: September 28, 2015

SNAP-Ed Sequel Statistical Analysis Plan

Methods: Up to 2 repeated online 24 hour dietary recalls using the Automated Self-Assisted 24-hour Recall (ASA-24) and the Diet History Questionnaire II (DHQ II) (web-based food frequency questionnaire) developed and provided by the National Cancer Institute will be used to estimate dietary intake; the Estimated Average Requirements (EAR) for nutrients (or Adequate Intake(AI) for nutrients that do not have an EAR) will be used as a dietary reference; the Healthy Eating Index-2010 will be used to characterize diet quality using data collected from the ASA-24; the 18-item US Household Food Security Survey Module (USHFSSM) will be used to assess household food security; the Nutrition Education Program (NEP) Medium Term Survey and additional questions will be used to assess participant characteristics, nutrition and health knowledge, and nutrition and health behavior

Characteristics: Study participant characteristics at baseline will be compared across the intervention and control groups to test for potential confounders to test for in regression models. Characteristics of participants who withdrew from the study will also be compared to those who completed the study.

Diet Quality: The Healthy Eating Index-2010 scoring algorithm will be used to characterize diet quality. Instructions and sample SAS code are provided by the National Cancer Institute website at <https://epi.grants.cancer.gov/hei/>. The simple algorithm will be used in order to assign HEI scores to each individual to be able to match and compare individual participants over time using regression modeling. Change in diet quality in the intervention group compared to the control group over time is one primary outcome.

Nutrient Intake: Mean usual nutrient intakes and distributions will be quantified at baseline and 1-year follow-up using the National Cancer Institute Method for estimating a single dietary component and change in intake from baseline and 1-year follow-up will be assessed and compared between the intervention and control groups. The website for instructions and SAS code are <https://epi.grants.cancer.gov/diet/usualintakes/>. Bootstrap methods will be applied to the data in order to estimate variability and compare mean usual intake estimates over time. Change in usual mean nutrient intake in the intervention group compared to the control group from baseline to 1 year follow-up is another primary outcome. The EAR for each nutrient will serve as the cutoff value to determine the percent of the population within the intervention and control groups that are at risk for nutrient inadequacy. Where an EAR does not exist, the percent of the population meeting or exceeding the AI will be used to determine the proportion of the population at low risk for nutrient inadequacy. The proportion of the populations at risk or at low risk is a third primary outcome and will be compared between the intervention and control groups and compared over the long-term to assess the impact of the intervention.

Food Security: The impact of the intervention on change in food security in the intervention group compared to the control group from baseline to 1-year follow-up will be assessed using a mixed regression model. Food security score may be used as a covariate in regression modeling or as a secondary outcome. Food security status will be characterized using the methods described in the US Guide to Measuring Food Security and in the USHFSSM survey.

Body Mass Index (BMI): BMI may be used as a covariate in regression modeling or as a secondary outcome.