Study Title: Improving the Quality of Food Assistance for People Living with HIV and Diabtes

NCT number: Not assigned

Original Document Date: March 21, 2019

Edited Date: April 10, 2019

Statistical Analysis Plan
B-FED pilot:
Statistical Power: Within this one year pilot study, we intend to recruit 100 participants to compare demographics, lab values, and glucose/insulin values between individuals in B-Fed versus those who are not. We intend to recruit at a 50/50 rate. With this sample size (50 per group), we will have 80% power to detect a difference of 0.57 standard deviations between group means using a two-tailed Type I error rate of 0,05. If effect sizes of this magnitude exist, then we are well positioned to identify them. However, we believe effect sizes smaller than this magnitude are clinically relevant. The purpose of this pilot study is to demonstrate the feasibility of consenting individuals to the study, the feasibility of training individuals to accurately provide a 24 hour diet recall, and estimate key parameters such as variances and correlations to allow the power calculation for a well-designed, accurately powered future study.

Data analysis: Descriptive statistics will be calculated for measures of central tendency (sample mean, sample median) and dispersion (sample variance, interquartile range) by group (those individuals enrolled in B-Fed vs those not). Histograms and Boxplots will be created to examine distributional properties of 24-hour diet recall information, hemoglobin levels, A1c, glucose, and other measures. Normal probability plots will be used to assess the appropriateness of a normality assumption. If a normality assumption is deemed appropriate, crude analysis will begin by using a two-sample t-test to compare change over time between the two groups. These analyses will be followed by Analysis of Covariance and multiple linear regression models to control for key covariates such as age, gender, race, and others. If the normality assumption appears violated, non-parametric tests, specifically Wilcoxon Rank Sum and non-parametric regression techniques will be applied. Careful attention will be given to residual variance estimation in order to guide a well-informed power calculation for an upcoming R18 submission.