Official Title: Feasibility of Delivering a Digital Behavioral Intervention to Increase Diet Quality Among Women Receiving WIC Benefits
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Analytic Approach

Primary Outcomes

Implementation will be assessed through intervention engagement calculated by dividing the number of days with valid tracking data (numerator) over the total number of possible tracking days (denominator). We will calculate and compare engagement rates by week. We will create a dichotomous outcome variable comparing high vs. low engagers using an established cutoff of 80% or more engagement in weekly self-monitoring [12,13]. Bivariate analyses using *t* tests and chi-square will be used to examine predictors of intervention engagement. Poisson regression with a robust variance will be used to examine sociodemographic differences among those with higher levels of engagement (80% or more weeks of tracking) and estimate risk ratios and 95% confidence intervals.

Preliminary efficacy will be measured by assessing changes in diet quality. Dietary intake will be measured using the ASA24 recall tool. Participants will be asked via email to complete 2 separate dietary recalls (1 week and 1 weekend day) within a 14-day period prior to enrollment and again upon study completion, for a total of 4 dietary recalls. These data will be used to calculate a Healthy Eating Index-2015 (HEI) score, which consists of 13 components, 9 of which assess adequacy of the diet, including 1) total fruit; 2) whole fruit; 3) total vegetables; 4) greens and beans (including peas); 5) whole grains; 6) dairy; 7) total protein foods; 8) seafood and plant proteins; and 9) fatty acids, which is a ratio of poly- and mono- unsaturated to saturated fatty acids. The remaining 4 assess dietary components recommended to be consumed in moderation: 10) refined grains; 11) sodium; 12) added sugars; and 13) saturated fats [9]. For all components, higher scores reflect better diet quality as moderation components are reverse scored. Each component is scored on a density basis rather than absolute scores, either as a percentage of calories or per 1000 calories allowing use of the HEI for a range of ages and populations. Summed scores of the 13 components yield a maximum total score of 100, with a higher score reflecting greater compliance with the 2015–2020 Dietary Guidelines for Americans [14].

Analysis
Data from this pilot study will be descriptive with outcomes being estimates of variables relating to feasibility [8]. Sample characteristics will be described as frequencies for categorical variables and means for continuous variables. HEI-2015 scores will be summarized as means and standard deviations and percent maximum score [(mean score/maximum score) x 100%]. We will explore intervention effects on change in HEI score from baseline to 12 weeks using a two-sample t-test. Although we will likely not have enough power, we will conduct exploratory analyses to assess differences in HEI scores among low vs. high engagers using linear regression. Similar analysis will be conducted for changes in relevant behavioral and psychosocial variables.

If the distribution of any outcome is heavily skewed, we will either appropriately transform the data so it's normally distributed or use a generalized linear mixed model with an appropriate link function. Sensitivity analyses will fit linear mixed models with a full maximum likelihood estimation using all available data to allow for responses to be missing at random, where the missing mechanism may be related to either observed covariates or response variables, but not related to the unobserved data. All analyses will be conducted using STATA 14 (StataCorp, College Station, TX).