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Statistical Analysis Plan

Official Study Title:

Indigenous Supported Agriculture Study (ISA) “Go Healthy”

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Data Analysis Plan for Indigenous Supported Agriculture Study (ISA) “Go Healthy”

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Aim: Conduct a randomized controlled trial to test the Go Healthy ISA program’s effect on diet, blood pressure, and blood lipids (primary outcomes) and on body mass index (BMI), hemoglobin A1c (HbA1c), food insecurity, and health status (secondary outcomes) among AI households.

All comparisons between the two randomized groups will be performed according to the principle of "intention-to-treat." We will analyze participants according to the group to which they were randomized, regardless of compliance to assigned intervention. Statistical comparisons will be performed using statistical analysis software (SAS, version 9.4), two-sided significance tests at an alpha of 0.05, and supplemented with the use of confidence intervals.

Baseline characteristics: Age, sex, highest level of education, marital status, household income, employment status, current smoking, current alcohol use, co-morbidities (chronic kidney disease, cardiovascular disease, diabetes, prediabetes, depression, anxiety, and hypertension), health care access, health care utilization, physical activity, enrollment in public assistance programs.

Primary Outcomes: Diet- Healthy Eating Index (HEI-2015), blood pressure, Systolic Blood Pressure (SBP) and Diastolic Blood pressure (DBP), blood lipids- low density lipoprotein cholesterol (LDL-C)

Secondary Outcomes: Food insecurity, body mass index (BMI), hemoglobin A1c, health status, and skin carotenoids

Power: The original power analysis for this study indicated that 167 households with one individual per household per group (n=334 total) would provide 80% power at a 0.05 significance level to detect a mean difference in SBP as low as 3.7 mmHg. Likewise, a sample size of 192 households with one individual per household per group (n=384 total) provided sufficient power to detect a mean difference in low-density lipoprotein cholesterol (LDL-C) as low as 8.6 mg/dL.

Statistical Analysis: We used an intention-to-treat analysis for all comparisons between the two randomized groups; therefore, we analyzed participants according to their randomized group, regardless of compliance with assigned intervention. For categorical baseline characteristics, we calculated the frequency and percent for the overall group and stratified by intervention group. To account for familial clustering, we compared baseline characteristics between the ISA intervention and wait-list control groups using generalized estimating equations for categorical variables. We present the p-values produced from these models to determine potential differences between the two groups.

All primary and secondary outcomes were continuous variables, and therefore we used linear mixed models to determine the effect of the ISA intervention on within-person change in separate models for each outcome while accounting for familial clustering. For systolic and diastolic blood

pressure (SBP and DBP), we used the average of the last two measurements for analysis. To compute levels of food security and insecurity, we will total the number of affirmative responses to items in the questionnaire, counting “Often” and “Sometimes” as affirmative. Consistent with USDA guidelines, 0-2 affirmatives indicate food security, and 3 or more affirmatives indicate food insecurity. We will calculate BMI by dividing weight by height squared (kg/m^2). For hemoglobin A1c we will use a continuous value and a binary indicator of 8%. For health status, we will use the general health question from the SF-36 and the EQ-5D-5L questionnaire. Skin carotenoids will be measured with a Veggie Meter, and we will use the average of 3 measurements for analysis. For each outcome, the initial model included a fixed effect for group assignment, a random effect for family, and a fixed effect for time (baseline or follow-up). We used the models to calculate the mean change in the outcome between baseline and follow-up, as well as the standard error and 95% confidence intervals stratified by intervention group. We used the p-values within each group to determine if there were statistically significant changes in the outcomes between baseline and follow-up within each group. Likewise, we used the p-values between the groups to determine if there were statistically significant differences in the outcomes between the groups. Since there was an imbalance in self-reported diabetes diagnosis between the intervention and control groups at baseline, we performed a sensitivity analysis where the variable for diabetes was added to the linear mixed models to adjust for an imbalance between the groups. We used Statistical analysis software (SAS, version 9.4) to perform statistical testing, two-sided significance tests at an alpha of 0.05 supplemented with the use of confidence intervals.