

Statistical Analysis Plan

Title: Building a Multidisciplinary Research Program to Address Hypertension Disparities: Exploring the Neurocognitive Mechanisms of a Self-Management Intervention for African American Women

NCT number: NCT04266704

Document date: 03/01/2019

Data Analysis Plan. Under the mentored guidance of Dr. Ploutz-Snyder, we will use version 15 of Stata IC statistical software setting two-tail alpha to reject null hypotheses at 0.05 (StataCorp, 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC). This is a development/pilot study that will develop the necessary procedures and materials (Aim 1) used to establish feasibility and acceptability (Aim 2) for conducting the research in our Ann Arbor setting, as well as a preliminary evaluation of the effects of the SAUCY intervention (Aim 3) on a small (n=50) sample. As such, our statistical reports will emphasize our desire to characterize the evidence (i.e. effect sizes) that may be used to inform larger future studies, in addition to reporting significance levels. Prior to final analyses, we will screen the data for data errors and missing data. Statistical assumptions will be tested, & appropriate data transformations or model adjustments will be used as needed. If the proposed statistical plan cannot be conducted after reasonable data/model adjustments, we will revert to alternative, possibly non-parametric techniques that address our aims. Given our prior experience with these outcomes and the proposed methods, we anticipate nominal missing data. Nevertheless, the methods we are proposing are robust to mild to moderate levels of missing data, and the statistical mentor of the proposed K-award, Dr. Ploutz-Snyder, is equipped to consider multiple imputation methods for handling missing data if needed.

Aim 1: Aim 1 focuses on developing and refining the intervention. Therefore, there is no data analysis plan.

Aim 2: Aim 2 focuses on feasibility and acceptability outcomes for subjects participating in our study. (See Table 3 for more detail.) Our primary outcomes for this aim are derived from previously used exit-interview and research participant satisfaction surveys that we will modify for the current research. These will reveal some quantitative, continuously measured scale scores for overall satisfaction, augmented by important qualitative items assessing subject satisfaction with their participation in the study. We will summarize the quantitative information in these surveys using standard descriptive statistics (means, sd, frequencies), however the qualitative exit-interview and survey information will be critical for our assessment of feasibility and acceptability, and for identifying potential subject-identified barriers and facilitators of participation that should be addressed for future research.

Aim 3: Aim 3 utilizes fMRI-derived brain activity data collected pre and post SAUCY (or control) intervention, with the hypothesis that women who receive the SAUCY intervention will have improved ability to differentiate between analytic and empathetic tasks, compared to women in the control group. The fMRI data will be preprocessed via a standard preprocessing stream that includes motion correction and slice timing corrections. We have experience with collecting these data and generating TPN, DMN, vmPFC task differentiation scores (see Figure 4) from a general linear model which will serve as our primary outcomes for this aim. These data are continuously scaled and normally distributed, with larger values indicating higher differentiation abilities. We will evaluate the effects of the SAUCY intervention in a group analysis using a 2-factor repeated-measures Analysis of Variance (ANOVA) that includes a Treatment (SAUCY, Control) effect, a Time (Pre, Post) effect, and the important Treatment by Time interaction term. We anticipate the interaction effect to reveal evidence that the SAUCY intervention is beneficial in improving these differentiation scores in the SAUCY group, relative to controls. As described above, our statistical report will emphasize the observed variance and effect size calculations to help inform a future randomized trial, in addition to reporting significance values.]