A Randomized Control Trial Treating Depression With Yoga and Coherent Breathing Versus Walking in Veterans

NCT03489122

Document Date: 3-20-2017

D.17. Data Management and Analysis Plan: The Data Coordinating Center at the Boston University School of Public Health will provide data management, including the development and maintenance of a REDCap database and the creation of a final database that will be sent to Dr. Silveri for statistical analysis, using SPSS 23.0. Descriptive statistics will be generated for baseline data and distributions between the yoga intervention and walking intervention will be compared using two-sample t-tests and chi-square or Fisher's exact tests to assess effectiveness of randomization. Descriptive statistics include means and standard deviations for continuous variables and group sizes and proportions for categorical variables. All analyses with be performed at the $\alpha = 0.05$ level of significance. Should groups have unequal distributions at baseline, relevant variables will be incorporated in subsequent linear models that will be used to examine intervention efficacy. In order to address the study aims of assessing the relative longitudinal change in dependent variables between yoga intervention and walking intervention groups over time, data will be collected at four time points, pre-randomization, and at weeks 4, 8, and 12. Mixed linear model analyses will be preformed focusing on the group x time interaction for the primary effects to be statistically modeled. These analyses will allow for inclusion of data at differing numbers of time points per subject if needed. We will examine different within-subject correlation structures for our interaction model and determine the optimal structure by comparing Akaike information criteria (AIC) values. The correlation structure that yields the lowest AIC will be adopted. Subjects who change antidepressant medications during the study will be included in intent to treat analysis, but will be co-varied for medication changes. Potential cohorts effects will be statistically addressed by controlling for group profiles, including group size, breakdown by sex of attendees, instructor, group parameters such as individual or group sessions, and group cohesion/overlap.