Statistical Analysis Plan

Study Title: Mindfulness Training in Healthy Older Veterans

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The primary behavioral analysis will use patients' scores for each outcome measure at each time point, using a mixed effects model with Treatment Group, Time, and the interaction term (Treatment Group X Time). The model will include age and education as additional predictor variables. Because there will be repeat assessments over time for each of the outcomes in both groups, the mixed effects model will allow us to assess differences in change between groups, while accounting for the correlation between assessments from the same individual. The model will include all participants who completed the baseline assessment and at least one session following MBSR or Brain Health (including those with incomplete data), which will reduce attrition bias and increase generalizability, power, and precision. The key value for hypothesis testing for the outcome measures will be the group-by-time interaction term.

The model assumes ignorable attrition; however, as the underlying assumption of missing at random is difficult to assess in practice, we will also conduct sensitivity analyses including only using those with complete data. Results will be compared across all analyses to assess the overall robustness of the findings. Since class wave, gender, number of classes attended, and baseline behavioral factors (e.g., baseline depression and anxiety scores) did not have a significant impact in our related study, these variables are not included in the model. However, we will conduct a preliminary analysis to evaluate effects of these variables on our pre-intervention data, and if no differences emerge as in our pilot study, data will be collapsed across these variables in the final analysis. Otherwise, significant variables will be included as additional predictor variables. We will assess statistical assumptions including normality of the residuals, and should a violation be identified, we will make transformations (e.g., logarithmic) or use generalized estimating equation approaches for non-normal data. To summarize, this analysis will allow us to: 1) evaluate our predictions described below, comparing the efficacy of the MBSR intervention over an active control intervention, and 2) evaluate any within-subject effects that occur between baseline and post-intervention across groups.