General Study Information

Principal Investigator: Ivana Croghan, PhD

A Study Title: A Feasibility study evaluating Mindfulness-Based Intervention Assessing A Wearable Wellness Brain Sensing Device (Muse-S™) in Practicing Health Care Providers.

Protocol date: 23 Sept 2024

Data Analysis

Data Analysis Plan:
Demographic characteristics are described using mean and standard deviations or frequencies and percentages based on the type of variable. For the primary aim of assessing feasibility, descriptive statistics and graphical displays will be presented for data obtained on frequency and duration of use over the 12 weeks of treatment. A linear mixed model with repeated measures for each time point that stress and sleep were taken will be utilized to estimate the association between the average of time spent using the Muse-S™ with the stress and sleep level outcome. Age, sex, and the total amount of meditation time at each interval will also be adjusted for in the model. As secondary outcomes, the results of the LASA, resilience, coping, and cognitive testing will be analyzed using linear mixed models with repeated measures to determine changes over time. In all cases, results will be summarized using point-estimates and corresponding 95% confidence intervals. Given the number of outcomes assessed, all analyses will be considered exploratory.

Endpoints:

Primary Hypothesis:
   a) HCP enrolled in this study will find the Muse-S™ Headband system easy to use and will use it often during the work week.

Secondary Hypotheses:
   a) Stress score will be lower and sleep score will be improved when compared to the baseline measures for those who use the Muse-S™ system as directed.
   b) As the use of the Muse-S™ system increases, QOL, resilience and coping will improve.