A Feasibility Study Evaluating Mindfulness-Based Intervention Assessing A Wearable Wellness Brain Sensing Device (Muse-S™) in Fibromyalgia Patients.

Study Analysis

NCT04720053

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General Study Information

Principal Investigator: Sanjeev Nanda, MD;

Co-principal investigators: Ivana Croghan, PhD; Ravi Ganesh, MD

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

Protocol date of most recent review and approval: 24 June 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. Differences in WPI and perceived stress were reported as baseline minus the end of study (day 90) value. A linear mixed model with repeated measures for each time point that WPI was taken will be utilized to estimate the association between percent of time spent in calm state with the WPI outcome. For each time interval, the percent of time spent in a calm state will be calculated by taking the average of the calm percentage during the interval. Age, sex, and the total amount of meditation time at each interval will also be adjusted for in the model.

Endpoints:

Primary Hypothesis: With an increase in the percentage of time spent in calm state, the WPI and perceived stress will be lower.