Title: Symptom Management Efficacy Study to Reduce Distal Neuropathy Pain
NIH NINR Grant No. 1R01NR017917-01
Institution: New York University
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Statistical Analytic Plan

Data distributions will be examined and transformed, if necessary. Baseline differences among groups will be compared with one-way ANOVA or Chi-Square analysis, as appropriate, and covariates with p-values < 0.10 will be assessed in efficacy models as potential confounders. Missing data mechanisms will be assessed prior to analysis and adjustment or blocking incorporated as appropriate. Between-group differences in repeatedly measured outcomes will be evaluated under intent-to-treat with LMMrm with fixed effects (treatment group and time); random effects (subject and intercept) and a covariance matrix for within-subject autocorrelation chosen by empirical modeling prior to inferential testing. We will test a separate model for each outcome without adjustment for multiplicity. Primary analyses will assess and pool controls if they test comparable to assess overall treatment affects, whereas secondary analyses will assess control group differences on efficacy estimates with apriori defined analyses. We will evaluate safety data with non-parametric statistics for rates, proportions and time to events. We will estimate the cross-sectional and longitudinal association between TCM diagnoses, neuro/NST assessment and pain medications with change in symptom severity using multiple correlation/regression analysis.