

The Innate Central Nervous System Immune Response to an Experimental Immune Challenge in People With Fibromyalgia

Statistical Analysis Plan

NCT04263454

Version Date: 02/16/2023

Jarred Younger, Professor, Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

Statistical Analyses

Statistical analyses were conducted with IBM SPSS for Mac version 27. Body temperatures measured in the left and right ear were averaged for each participant. Baseline data were compared between groups using independent-samples t-tests.

Brain metabolite levels were expressed as ratios over the local CR concentration. Brain temperatures below 35.0°C and above 42.0°C were excluded as an additional data quality control measure, as temperatures outside of this range are not physiological. Mixed analyses of variance (ANOVA) were conducted with time as the within-subjects factor (levels: pre-endotoxin, post-endotoxin) and study group as the between-subject factor (levels: FM, healthy control). Endotoxin dose (0.4ng/kg vs 0.3ng/kg) and its interaction with time was added as an additional between-subjects factor, and age and the age-by-time interaction was entered as a covariate of no interest. The effects of interest were the time-by-group interaction (to test whether FM and HC participants exhibited different responses to endotoxin) and the dose-by-time interaction (to test whether participants receiving 0.3ng/kg versus 0.4ng/kg endotoxin exhibited different responses). Significant interactions were followed up with repeated-measures t-tests assessing the effect of time separately for FM patients and HCs. The dependent variables were brain temperature, CHO/CR, NAA/CR, and MI/CR in the 47 brain regions. Because of the small sample size and lack of statistical power, all tests were considered significant at $p < 0.05$. However, all tests meeting a more stringent false discovery rate threshold are highlighted. The false discovery rate threshold of 0.05 yielded a corrected p-value threshold of 0.0113.