Light Therapy for Moderate Traumatic Brain Injury

NCT02233413

Statistical Analysis

6.26.20

Statistical Analysis

All statistical analyses were performed using R Language for Statistical Computing (version 3.6.0). Differences and relations were considered statistically significant at $p<0.05$. All results are presented as mean + standard deviation (S.D.) unless noted otherwise. Baseline differences across groups were compared via using one-way ANOVA for continuous variables (e.g., Age, RPQ scores) and via Chi-Square test for categorical variables. To test neuroreactivity of LLLT via its effect on the diffusion tensor parameters, we used a linear mixed effect (LME) model with treatment (light therapy vs. sham) and time point (acute, early sub-acute, late sub-acute) as fixed effects, and tract and time point nested within each patient as random effects. All patients with at least one MRI were included in this analysis. Conformity of the data to statistical assumptions were checked by investigating QQ plots of the data. LME models, which are akin to multiple regression models that can account for correlations due to repeated measures, have several advantages in this context. LME modeling allowed us to pool all our data --- i.e., across treatment groups and three time points, as well as across all 18 tracts --- to examine relationships robustly. Moreover, because the LME model allows partially repeated measures, it can accommodate data from subjects with missing timepoints (e.g., missing MRI sequences). In addition, the LME model treats each timepoint as a separate variable. Therefore, any baseline difference in DTI parameters across the LLLT and sham groups did not confound the overall analysis enabling one to robustly identify differences in DTI parameters across the treatment groups while explicitly accounting for repeated measurements, within-tract and within-subject correlations, and missing time points.

A similar LME model (treatment group and time point as fixed effects, and patient as a random effect) was used to test for the effect of LLLT on clinical symptoms). The *p* values for the fixed effects in the LME model were calculated using type III analysis of variance table with Satterthwaite's degrees of freedom method.