Transcranial Photobiomodulation for reducing autism symptoms in children.

March 19, 2024

Data Collection and Statistical Analysis
Primary Analyses

The last author, a licensed psychologist experienced in the use of CARS in clinical practice, conducted blinded Before and After CARS ratings for all participants. The final CARS evaluations were performed immediately after the final treatment session. CARS scores were analyzed using the independent sample t-test. We compared the differences from the baseline between both groups, calculating both the average difference and 95% CI within each group and between groups.

Outcomes
Baseline Data

At the beginning of the trial, an initial evaluation was performed to assess the severity of ASD in participants using the CARS score. **Table 1** displays the mean, median, and range of the participant scores. Most participants had moderate to severe ASD, with a CARS score higher than 35. There were no significant differences in age, gender, ethnicity, language status, treatment status, or CARS scores between the Active and Sham groups.

Primary Outcome

Every participant who completed the trial was evaluated with CARS post-treatment. There were no missing CARS posttreatment evaluations. In the Active group, the before treatment CARS scores had a mean score value of 43.5 (n = 16) with a standard deviation (SD) of 5.7, the after-treatment scores had a mean score of 33.7 with an SD of 5.0. In the Sham group, the before treatment CARS scores had a mean score value of 40.6 (n = 14) with SD of 7.2, the after-treatment scores had a mean score of 38.0 with SD of 8.4. **Table 3** shows the mean (M) and SD of the CARS scores for the Active and Sham groups before and after treatment. The difference in the change in CARS between the two groups was 7.23 (95% CI 2.357 to 12.107, p=0.01).
In addition to analyzing the changes in CARS scores based on averages, we also conducted respondents-based analyses, quantifying the number of participants in Active and Sham groups, whose change in CARS was greater than 4.5 points (as it has been suggested by Jurek et al 2022 to be the minimal clinically important difference). The result was significant X_2=8.48, p=.004. By the end of the trial, 87% of the participants in the Active group (14) had achieved an equal or greater than 4.5-point reduction in CARS scores, only 35% of the participants of Sham group (5) achieved an equal or greater than 4.5-point reduction in CARS scores. The number of subjects that achieved this minimal clinically important difference in the Active group was statistically significantly higher compared to the Sham group. Therefore, the treatment was considered to have clinically meaningful efficacy.