**Supplemental Digital Content (SDC) for Puccio et al.**

**SDC 3.** Summary of anthropometric results by study visit (MMRM analysis)

|  |  |  |  |
| --- | --- | --- | --- |
| **Age at Study Visit** | **Test (n = 88)** | **Control (n = 87)** | **Difference Between Groups\*** |
| **LS Mean (SE)** | **LS Mean (SE)** | **Difference** | **95% CI** | **P-value** |
| **Weight, kg** |
| 1 month | 4.32 (0.08) | 4.33 (0.07) | -0.02 | -0.23, 0.19 | 0.872 |
| 2 months | 5.28 (0.08) | 5.32 (0.08) | -0.03 | -0.24, 0.18 | 0.752 |
| 3 months | 6.07 (0.08) | 6.13 (0.08) | -0.07 | -0.28, 0.15 | 0.533 |
| 4 months | 6.74 (0.08) | 6.79 (0.08) | -0.04 | -0.26, 0.17 | 0.683 |
| 6 months | 7.70 (0.08) | 7.74 (0.08) | -0.04 | -0.26, 0.17 | 0.686 |
| 12 months | 9.75 (0.08) | 9.77 (0.08) | -0.01 | -0.24, 0.21 | 0.902 |
| **Length, cm** |
| 1 month | 54.19 (0.19) | 54.21 (0.19) | -0.014 | -0.53, 0.51 | 0.956 |
| 2 months | 57.80 (0.20) | 57.86 (0.19) | -0.067 | -0.60, 0.47 | 0.804 |
| 3 months | 60.62 (0.20) | 61.09 (0.19) | -0.472 | -1.02, 0.07 | 0.088 |
| 4 months | 63.46 (0.20) | 63.65 (0.19) | -0.187 | -0.74, 0.36 | 0.502 |
| 6 months | 67.50 (0.20) | 67.59 (0.19) | -0.082 | -0.64, 0.47 | 0.770 |
| 12 months | 76.00 (0.22) | 75.97 (0.21) | 0.031 | -0.56, 0.62 | 0.918 |
| **Body Mass Index, kg/m2** |  |  |  |  |  |  |  |
| 1 month | 14.67 (0.14) | 14.72 (0.14) | -0.05 | -0.43, 0.33 | 0.803 |
| 2 months | 15.80 (0.14) | 15.86 (0.14) | -0.06 | -0.45, 0.33 | 0.760 |
| 3 months | 16.50 (0.15) | 16.41 (0.14) | 0.09 | -0.30, 0.49 | 0.636 |
| 4 months | 16.73 (0.15) | 16.71 (0.14) | 0.01 | -0.39, 0.41 | 0.953 |
| 6 months | 16.89 (0.15) | 16.91 (0.14) | -0.03 | -0.43, 0.38 | 0.898 |
| 12 months | 16.88 (0.16) | 16.86 (0.15) | 0.02 | -0.40, 0.44 | 0.917 |
| **Head circumference, cm** |  |  |  |  |  |  |  |
| 1 month | 37.27 (0.14) | 37.38 (0.14) | -0.11 | -0.50, 0.28 | 0.581 |
| 2 months | 39.04 (0.15) | 39.11 (0.14) | -0.08 | -0.47, 0.32 | 0.710 |
| 3 months | 40.41 (0.15) | 40.48 (0.14) | -0.07 | -0.47, 0.34 | 0.746 |
| 4 months | 41.57 (0.15) | 41.66 (0.14) | -0.10 | -0.51, 0.31 | 0.639 |
| 6 months | 43.69 (0.15) | 43.39 (0.15) | 0.30 | -0.11, 0.71 | 0.156 |
| 12 months | 46.32 (0.16) | 46.29 (0.16) | 0.03 | -0.41, 0.47 | 0.896 |

CI, confidence interval; LS, least squares; MMRM, mixed-effect model repeated measures; SE, standard error.

\*From MMRM analysis including baseline anthropometric assessments as a covariate and sex, center, visit, treatment, sex x visit, and sex x treatment as fixed effects.