

***Delineation of Sensorimotor Subtypes Underlying Residual Speech Errors  
(C-RESULTS-SCED)***

***Protocol NCT03736213***

***Document generated 2/2/2018***

### **Statistical Design and Power: Study 3**

For inferential statistical analysis, a randomization test will be conducted for each participant. Each randomization test will compare the two biofeedback types (ultrasound and visual-acoustic) with respect to F3-F2 difference for the 25 /r/ trials measured in each session. In a previous randomization study comparing biofeedback and non-biofeedback treatment in 7 children with RSE, the median effect size of the difference between treatment conditions ( $d_2$ ) was calculated to be 3.0. Calculations using GPower indicate that our proposed within-participant comparison (10 observations in each condition) has 90% power to detect an effect of this magnitude. We do not currently have data to estimate the likely magnitude of the difference between visual-acoustic and ultrasound biofeedback conditions in individuals with asymmetric sensory profiles. However, relying on a precedent established in previous single-case studies of treatment efficacy and upheld throughout our own previous research, we will treat  $d_2 = 1.0$  as the minimum difference between conditions that will be considered clinically significant. (That is, the difference between conditions must be at least as great as the pooled standard deviation). Our proposed within-participant comparison has power of .80 to detect this minimum effect size of interest. In addition, these power calculations ignore the fact that we will have 20 observations in each session; models that incorporate the nested structure of the data would presumably reflect higher power.

Randomization tests are computed within-subject, and we propose to replicate this comparison across 8 participants. As described in **Aim 3**, participants enrolled in Study 3 will be required to exhibit an asymmetric profile of sensory sensitivity. This requirement for asymmetric sensory acuity will allow us to use within-subject comparisons to test the hypothesis that sensory acuity in a domain mediates response to the type of biofeedback that targets that domain. Although we do not yet have estimates of the prevalence of such asymmetries in the population of children with RSE, our pilot data suggest that asymmetric sensory profiles occur in roughly 8% of typically developing young adults. Assuming that asymmetries occur at the same rate in the population of children with RSE, our overall sample of 118 children is estimated to yield between 9 and 10 individuals who meet criteria for Study 3. Based on our previous work, we anticipate that not all participants will show a significant randomization test result, but those who do will show an advantage for the congruent over the incongruent condition, and not the reverse.