

Title:

Screening for Autism Spectrum Disorders Using Auditory Brainstem Responses

Number: NCT03971578

Date: May 30, 2019

Project Funded by NIH NIDCD SBIR Grant R43DC018430-01 to Intelligent Hearing Systems Corp.

Grant Title:

Screening Device for Autism Spectrum Disorders using High Stimulation Rate ABR with Continuous Loop Averaging Deconvolution

Statistical Analysis Plan

Hypothesis: The detection of neurological anomalies can be accentuated by increasing the physiological demand on neural pathways by increasing the stimulation rate (Fujikawa-Brooks et al., 2010) and therefore increasing the specificity and sensitivity of ABR testing for ASD screening.

Rationale: The purpose of this experiment is to demonstrate that higher stimulation rates, achieved using the CLAD technique (Delgado and Ozdamar, 2004), will show differences in ABRs between age-matched populations of children with and without ASD. Although the increase in rate will also increase peak latency and decrease amplitudes, the ASD population is expected to show a greater latency shift effect and increase the specificity and sensitivity of ABR testing for ASD screening. Previously, Fujikawa-Brooks et al. (2010) used a maximum rate of 61/sec and showed a significant rate effect. Because of the time constraints of a Phase I feasibility study, testing of the target population, newborns, is not possible because a confirmed ASD diagnosis will not be available for several years. The researchers recognize that there are age related differences in ABR latencies; however, these have been well documented in a normal population. The use of an age-matched control group will provide a comparison to control for normal developmental changes in ABR latencies.

Factor: Click stimulation rate (five levels): 19, 39, 61, 120, and 250 per second. The three lower rate levels were selected to replicate previous research. The upper levels were selected to obtain ABRs with discernible peaks while challenging the neural transmission of the auditory system.

Dependent Variables: Absolute peak latencies and amplitudes, and right-left ear differences of both.

Analysis: Analysis of variance and t-tests will be conducted to determine rate effects. Sensitivity and specificity measures will also be conducted for each rate at various

References:

Delgado, R.E., Özdamar, Ö. (2004). Deconvolution of evoked responses obtained at high stimulus rates, *Journal of the Acoustical Society of America*, 115:1242–1251.

Fujikawa-Brooks, S., Isenberg, A. L., Osann, K., Spence, M. A., & Gage, N. M. (2010). The effect of rate stress on the auditorybrainstem response in autism: A preliminary report. *Int J Audiol*, 49(2), 129–140. <https://doi.org/10.3109/14992020903289790>