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Occupations as an Outcome Measure in a Clinical Trial: Fragile X Syndrome and Sertraline (Preliminary Results)

Jennifer Sik
Dominican University of California

Michelle Beckwith
Dominican University of California

Brina Nguyen
Dominican University of California

Kenneth Yu
Dominican University of California

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Fragile X Syndrome (FXS) is the most common form of inherited intellectual and developmental disability, and a known genetic cause of autism. Individuals with FXS present with deficits in cognition, social skills, behavior, language and sensory processing skills; all of which are commonly assessed through standardized and norm-referenced assessments. However, these outcome measures are sometimes not sensitive to contextually based changes in daily life. Further, there is limited research employing qualitative methods in the FXS literature. The purpose of this research was to examine family perspectives collected via semi-structured interviews as part of a randomized controlled medication trial of sertraline (Zoloft®) on children two to six years old diagnosed with FXS. The constant comparison method was used to analyze differences in family expressions of their child's improvements over the course of the 6-month clinical trial. Twelve interviews were analyzed, six-treatment, six-placebo, and all coding was done blind to group assignment. Results indicated greater improvements in the treatment group when compared to the placebo group in: anxiety, receptive / expressive communication, maladaptive behaviors and some sensory issues. These preliminary findings are encouraging warrant a need for further research with a larger sample.