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Effects of Sertraline Treatment for Young Children with FXS

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Effects of Sertraline Treatment for Young Children with FXS

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INTRODUCTION AND PURPOSE
Selective serotonin reuptake inhibitors (SSRIs) help treat many of the phenotypic manifestations of fragile X syndrome (FXS) including anxiety, sensory processing challenges, and communication and intellectual deficits. However, the efficacy of SSRIs has not been previously studied in children with FXS under five-years-old. The purpose of this study was to elucidate group differences in behavior and developmental outcome measures for young children with FXS when treated with sertraline compared to placebo.

PARTICIPANTS and DESIGN
• 57 participants with FXS, ages 2 – 6 years old (mean 3.9 years; SD 1.1)
• Randomized, 6-month, double-blind, placebo-controlled trial of sertraline (Zoloft)
• Baseline and post-treatment outcomes measured
• Primary outcomes: Mullen Scales of Early Learning (MSEL) expressive language subscales and Clinical Global Impression Scale-Improvement (CG-I)
• Secondary outcomes: MSEL fine motor, visual reception, and receptive language subscales; Autism Diagnostic Observation Schedule, Second Ed. (ADOS-2); Visual Analog Scale (VAS); Sensory Processing Measure-Preschool (SPM-P); and Preschool Language Scale, Fifth Ed. (PLS-5)
• Randomized, 6-month, double-blind, placebo-controlled trial of sertraline (Zoloft)

RESULTS

Consolidated Standards of Reporting Trials (CONSORT)

Effect Sizes of Sertraline on Mullen Scales of Early Learning Secondary Measures

Comparison of Adverse Events

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