Effects of Sertraline Treatment for Young Children with FXS

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INTRODUCTION and PURPOSE

Phenotypic manifestations for young children with fragile X syndrome (FXS) include: anxiety, sensory processing challenges, global language and communication deficits and intellectual and developmental disabilities. Many of these symptoms can be treated with medications, including selective serotonin reuptake inhibitors (SSRIs). However to date a clinical trial has not been conducted for children under five years old.

This study investigated the following question:

**Are there group differences on developmental outcome measures for those children treated with sertraline compared to placebo?**

PARTICIPANTS and DESIGN

- 30 children, FXS full mutation, 24-68 months
- Randomized, 6 month controlled trial of sertraline (Zoloft)
- Baseline and post-assessment design
- Randomized, 6 month controlled trial of sertraline
- Assessors and subjects blind
- Research team professionals and outcome measures from the following disciplines: medicine, occupational therapy, psychology, education and speech pathology

RESULTS

Sertraline Post 16.1 19.4 15.3 23.9 16.9 15.6 18.1
Placebo Post 21.9 24.7 15.8 26.3 17.6 18.1 18.8
Sertraline Baseline 18.3 20.3 16.6 26.1 16.2 17.7 19.8
Placebo Baseline 20.8 25.3 16.9 29.7 18.5 19.6 18.9
Sertraline Post 32.9 27.4 29.1 26.3 64.5
Placebo Post 42.3 24.3 23.6 20 54.3

Social Participation Raw Score, f(1,24) = 6.65, p = .016, eta² = .22

SOC Raw VIS Raw HEA Raw TOU Raw BOD Raw BAL Raw PLA Raw

Mullen Raw Scores

Mullen Mean Raw Scores and ELC Standard Score

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SIGNIFICANT IMPROVEMENTS in the sertraline treatment group found in:

- General functioning
- Overall behavior, specifically hyperactivity, impulsivity and attention
- Cognition
- Social Participation: family social events and community activities

IMPROVEMENTS in behavior, particularly hyperactivity, impulsivity and attention may influence improved social participation in family activities and the community and thus overall family quality of life.

UNIQUE interdisciplinarity and collaborative approach to a clinical trial.

EXPERTISE from scientists and clinicians from the fields of medicine, occupational therapy, psychology, education, speech language pathology

A collaborative and interdisciplinary approach to research is a mirror to what best practices are for intervention for children with FXS. Our research provides a model for future clinical trials.

SELECTED REFERENCES


Acknowledgements and Contacts

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