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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
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
- Assessors and subjects blind
- Research team professionals and outcome measures from the following disciplines: medicine, occupational therapy, psychology, education and speech pathology

RESULTS

Social Participation Raw Score, f(1,24)= 6.65, p = .016, eta^2 = .22

No significant differences between groups found on side effects:
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

CONCLUSIONS

- Significant improvements for 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 interdisciplinary and collaborative approach to a clinical trial.

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Our sincerest thanks to the FXS families who participated in this study and to the FXS community for supporting this research.
MIND Institute Sartraline Team: Lauren Bishop, Salpi Siyahian, Tasleem Chechi, Jonathan Polussa, Susan Harris, Andrea Schneider, Kerrie Lemons Chitwood, Kylee Cook, Beth Goodlin-Jones, David Hessl, Pam Gallego, Louise Gain, Michele Ono and Julie Morcillo

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SELECTED REFERENCES

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