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Effects of Sertraline Treatment for Young Children with FXS

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INTRODUCTION and PURPOSE

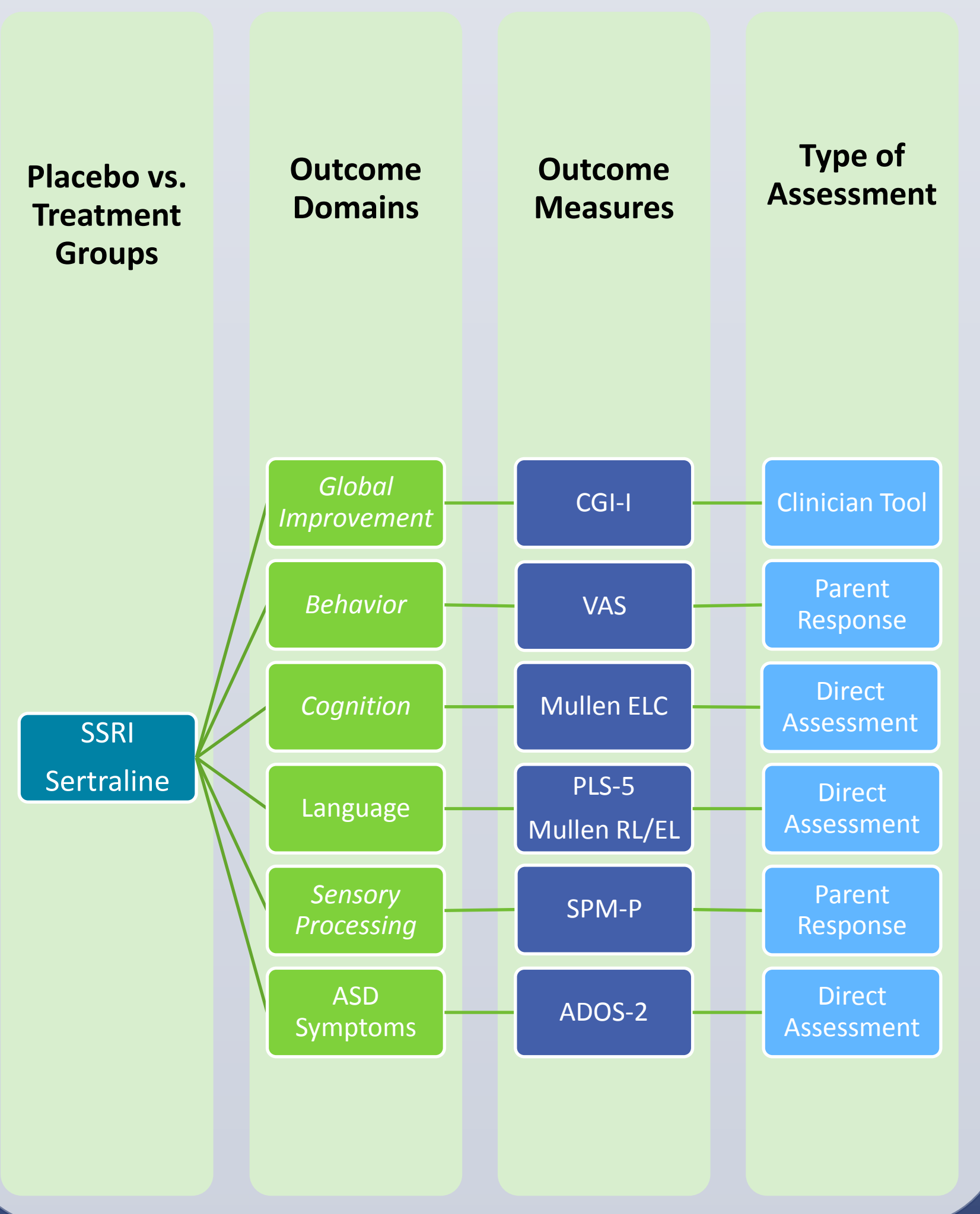
Phenotypic manifestations for young children with fragile X syndrome (FXS) include: anxiety, sensory processing challenges, global language and communication deficits and intellectual and developmental disabilities. Many of these symptoms can be treated with medications, including selective serotonin 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:

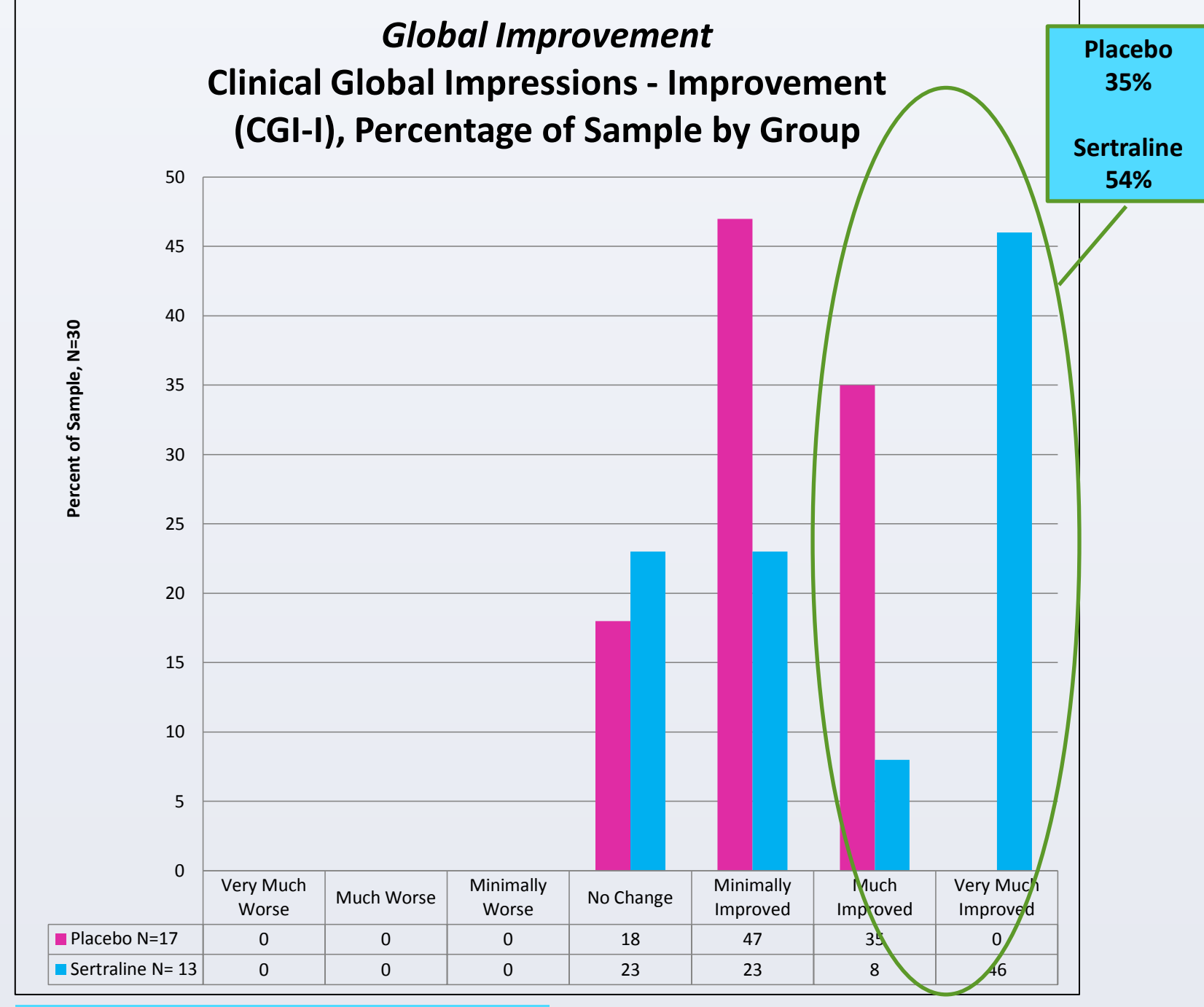
Are there group differences on developmental outcome measures for those children treated with sertraline compared to placebo?

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



$\chi^2 (3, N=30) = 11.52, p = .009.$

Parent Defined Target Symptoms Scale - Visual Analogue Scale (VAS-Targeted Behavior)

Date: 13 AUG 13 Subject No: 5000010 287

Placer Initials: M... Subject Initials: ...

Describe and Rate the three target behaviors for this study.

1. Target Behavior: Attention

Put a vertical line across the line corresponding to the severity of the subject's target behavior.

Worst behavior _____ Behavior not a problem _____

2. Target Behavior: Headflapping, sensory issues

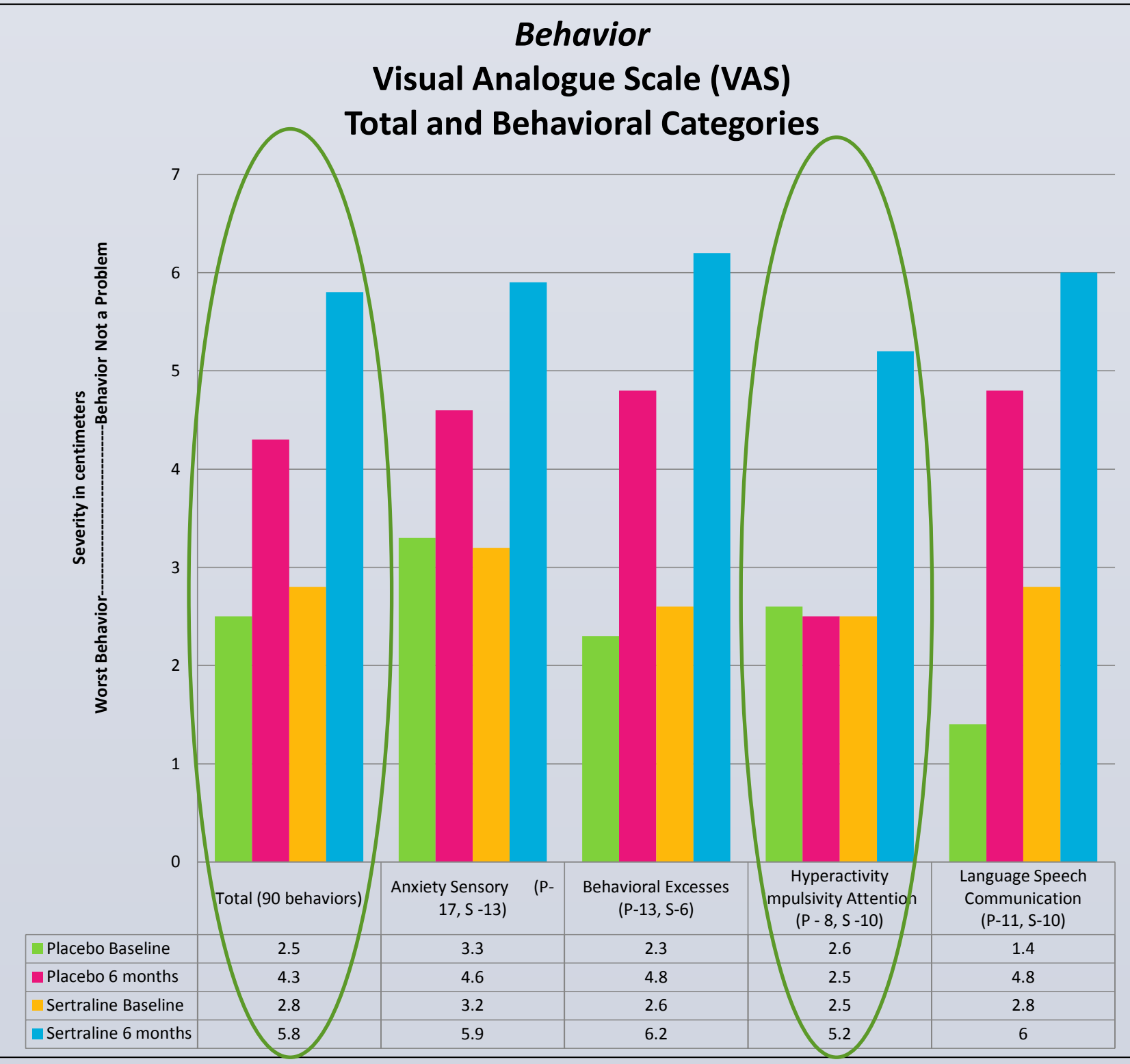
Put a vertical line across the line corresponding to the severity of the subject's target behavior.

Worst behavior _____ Behavior not a problem _____

3. Target Behavior: Spells

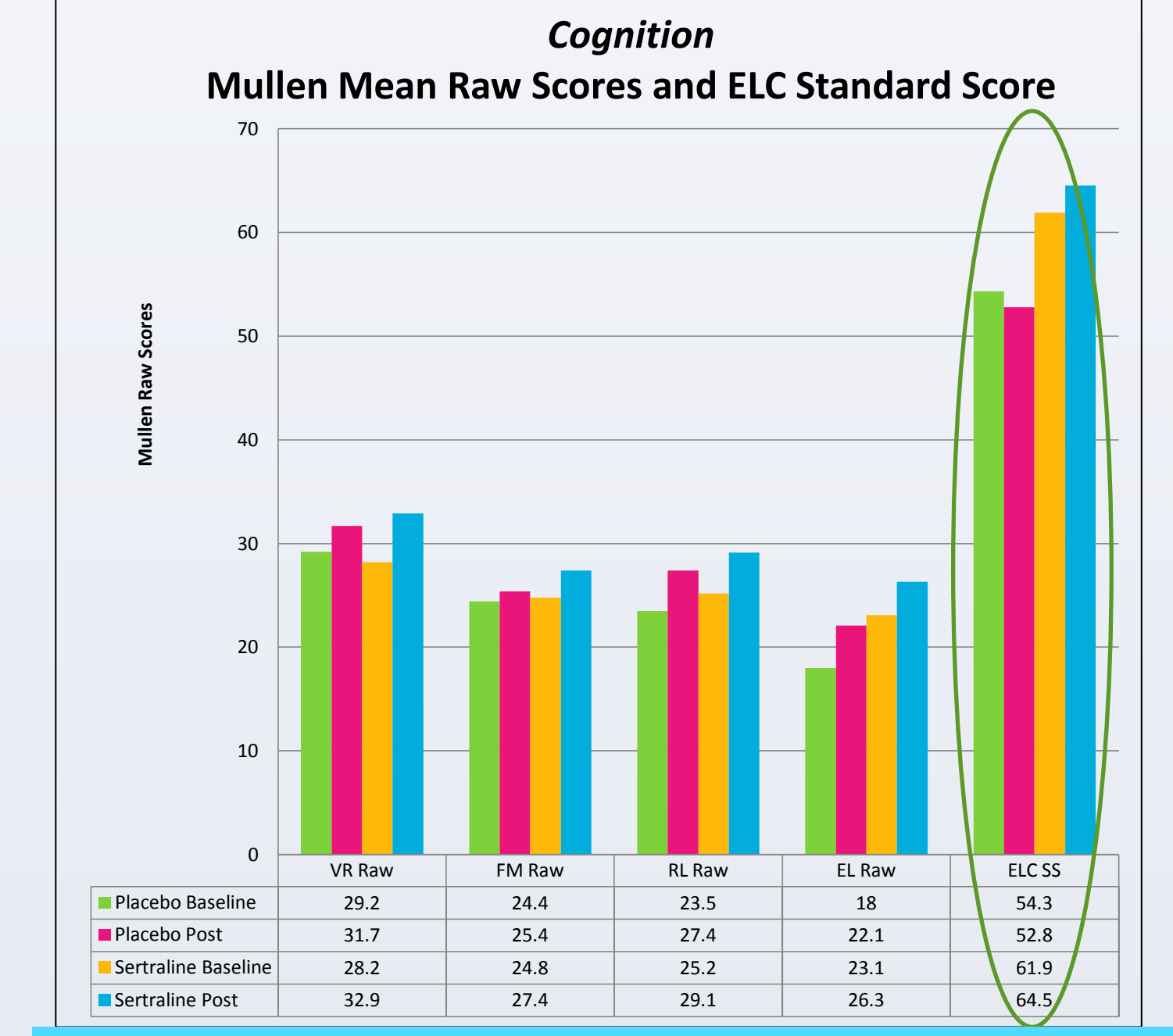
Put a vertical line across the line corresponding to the severity of the subject's target behavior.

Worst behavior _____ Behavior not a problem _____

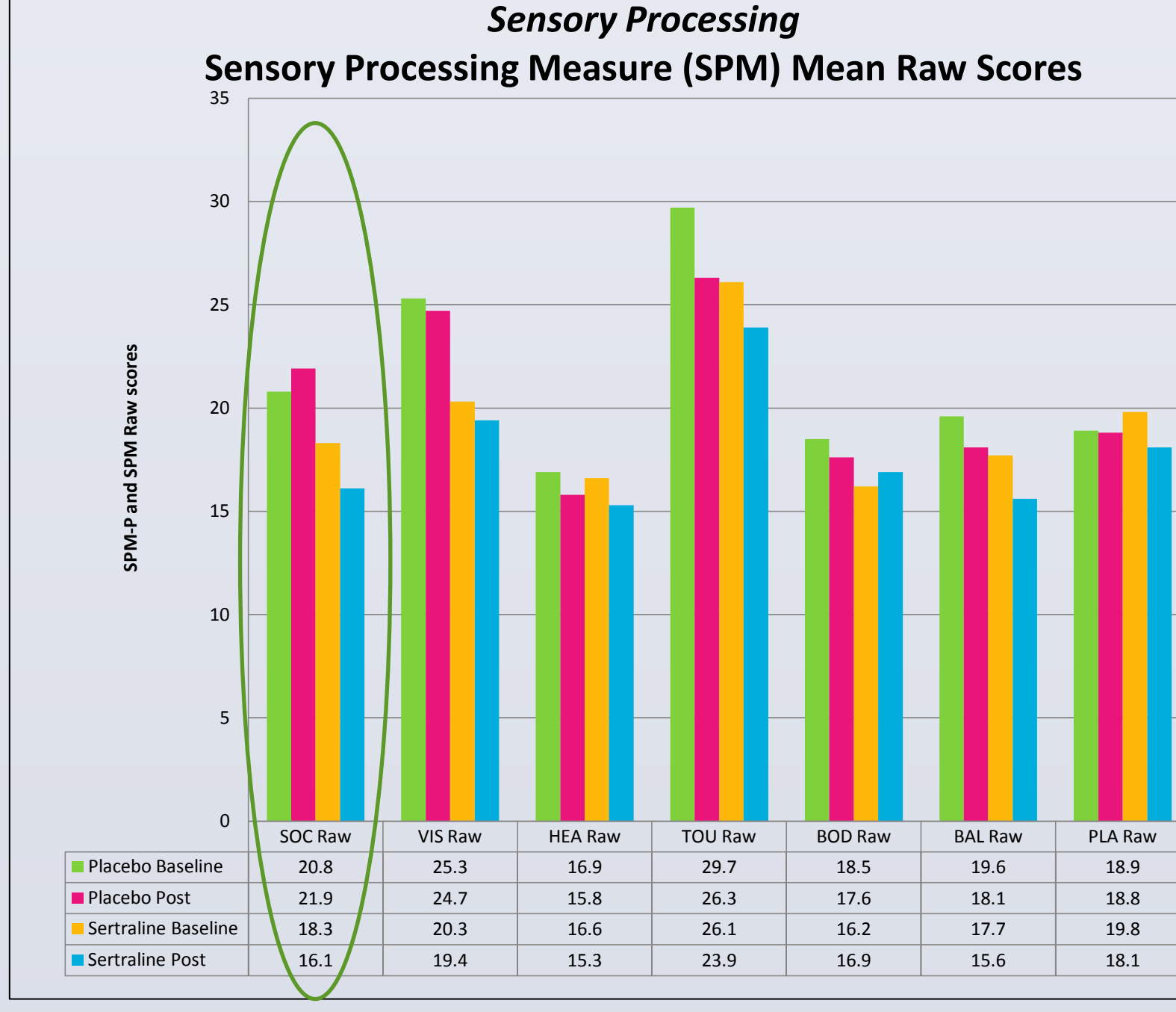


Total Behaviors, $F(1,88) = 4.36, p = .040, \eta^2 = .047$
HIA - $F(1,16) = 6.33, p = .023, \eta^2 = .284$

RESULTS



Early Learning Composite (ELC), $F(1,28) = 3.79, p = .062, \eta^2 = .119$



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

Social Participation Item Analysis: Family outings, gatherings, activities with friends and family errands

Summary of All Reported Adverse Events Reported. Placebo, N=103 Reported Adverse Events, Sertraline Treatment, N=68 Reported Adverse Events.

Adverse Event	Placebo (N=103) Frequency (Percent)	Sertraline Treatment (N=60) Frequency (Percent)
Severity		
Mild	79 (76.7)	54 (79.4)
Moderate	20 (19.4)	13 (19.1)
Severe	4 (3.9)	1 (1.5)
Total	103 (100)	68 (100)
Adverse Event Type		
Behavior	11 (10.7)	4 (5.9)
Bruising after playground	1 (1.0)	0 (0)
Decreased Verbalization	1 (1.0)	0 (0)
ER visit (vomit after falling)	0 (0)	1 (1.5)
GI Upset	43 (41.7)	32 (47.1)
Infections	28 (27.2)	25 (36.8)
Neurological Symptoms	15 (14.6)	4 (5.9)
Skin	4 (3.9)	2 (2.9)
Total	103 (100)	68 (100)

Note. Behavior (anxiety, aggression, hyperactivity, self-stimulatory behavior); GI upset (vomiting, diarrhea, loose stool, constipation, appetite loss); Infections (upper respiratory, ear, eye, sinus, flu, cold, cough, fever, balanitis); Neurological Symptoms (excessive tiredness, headache, seizures, tremor, drooling); and Skin (rash, itching, swelling, diaper rash).

No significant differences between groups found on side effects:
Severity: $\chi^2 (2, N=171) = .856, p = .652$
Adverse event type: $\chi^2 (7, N=171) = 8.26, p = .310$

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.
 - ✓ 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.

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