

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



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## Background

Fragile X Syndrome (FXS) is the most common form of inherited intellectual and developmental disability.

- ◆ Offers a **genetic model** to understanding autism spectrum disorder
- ◆ Manifests with **behavioral** problems, **anxiety**, and **sensory processing** difficulties

A battery of standardized, norm-referenced assessments and parent checklists are frequently used as **outcome measures** in clinical trials.

- ◆ The addition of **interview methods** will provide family voice and personal stories thus affording:
  - An **occupation-centered** lens to empirically examine living with FXS and the **impact** on family life
  - A measurement for **contextually-based changes** as an outcome measure for use in clinical trials

(Hagerman, Hoem, & Hagerman, 2010; Hagerman, Lauterborn, Au, & Berry-Kravis, 2012; Hess et al., 2016; Hessel et al., 2016; NFXF, 2016; Wang, Berry-Kravis, & Hagerman, 2010).

## Research Question

Can qualitative interview methods serve as an outcome measure capturing changes in occupational performance between treatment and placebo groups?



## Methods

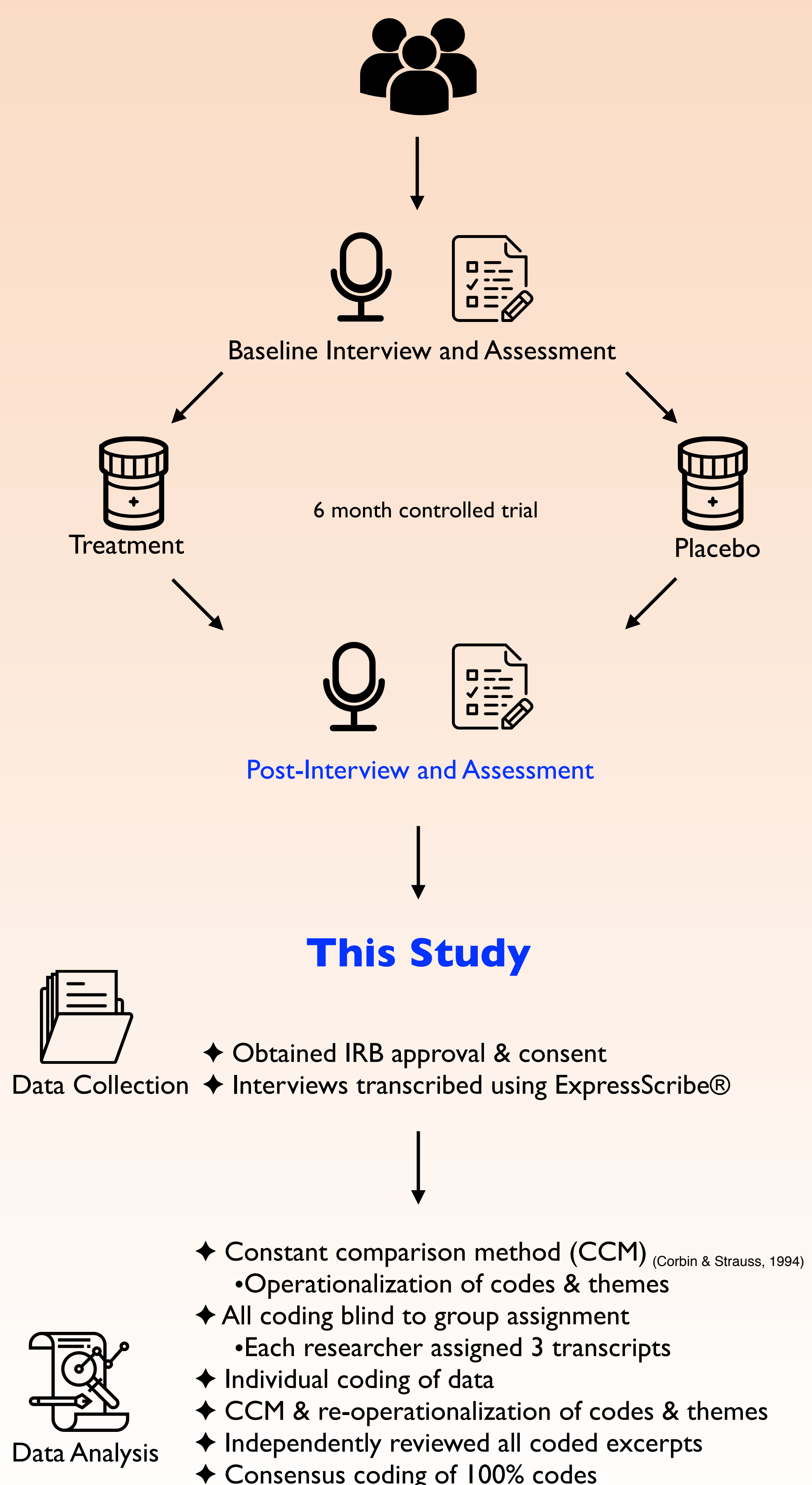
Design: Qualitative (interview methods)

Population: Families with children diagnosed with full mutation FXS enrolled in UC Davis MIND Institute sertraline (Zoloft®) clinical trial

Interview sample for this study

- 12 interviews
- 6 placebo
- 6 treatment

UC Davis MIND Institute RCT (Hess et al., 2016)



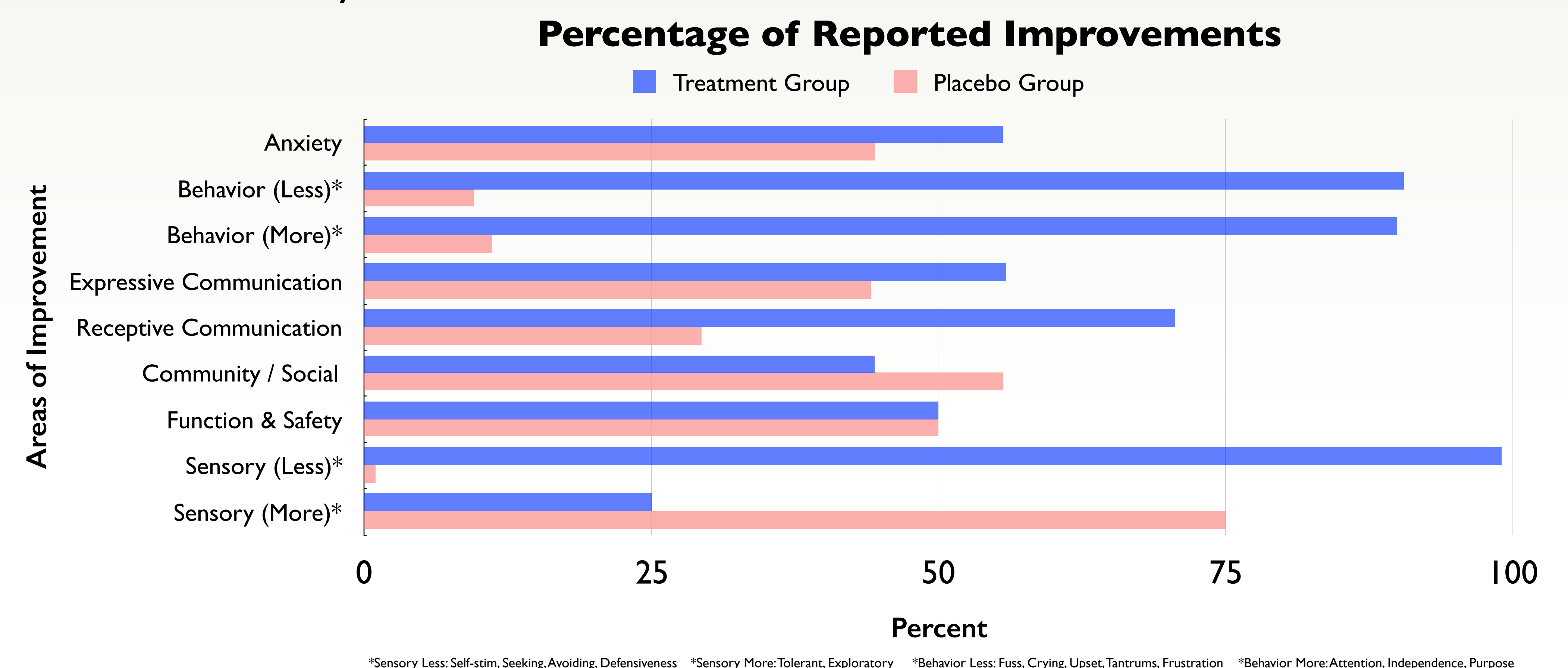
## Results

Preliminary trends indicated improvements in the sertraline treatment group compared to the placebo group in the following areas:

- ◆ Anxiety
- ◆ Expressive & receptive communication
- ◆ Maladaptive behaviors
- ◆ Sensory (Less)

The sertraline group did not show greater improvements than the placebo group in the following areas:

- ◆ Community/social
- ◆ Sensory (More)



### Sample Interview Question and

"Have you noticed any changes related to anxiety/communication/behavior/sensory? How has that impacted you as a family?"

#### Anxiety

"I think he maybe is on the real meds because he is sort of dealing with his anxiety better. I am finding that it's not such of a struggle. His episodes aren't as big. They are still there. He's getting better at transitioning into getting into the next thing."

#### Communication

"He has improved tremendously. He is using more signs, he is very expressive, he uses his facial expressions to show us how he is feeling."

#### Behavior

"He has calmed down. He's more interactive with play. Doing his own play things, playing with his sister or brother or playing by himself."

#### Sensory Strategies/Community & Social

"I think the fact that we expose him to so many things, like grocery shopping. So he is not afraid of being in a big noisy space with lights."

## Conclusion

- ◆ This preliminary data did show differences between groups in several areas
- ◆ Occupational therapy intervention and clinical research should include parent perspectives, not just standardized assessments
- ◆ Families within the FXS community felt a sense of altruism from participating in the study
- ◆ Future directions to include a larger sample for analysis

## Acknowledgments

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