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TITLE: Efficacy of the Direct Instruction Language for Learning Program to Promote Expressive and Receptive Language in Children with Autism Spectrum Disorder

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<b>13. SUPPLEMENTARY NOTES</b>  Nothing to report					
<b>14. ABSTRACT</b> As many as 75% of children with autism spectrum disorder (ASD) have language delay ranging from moderate to extreme. Many interventions have been developed to address language delay including intensive treatment using applied behavior analysis (ABA). Although often effective for severe language delay (e.g., children with no language), intensive ABA intervention may not be needed for children with moderate language delay. Untreated moderate language delay predictably interferes with the child's ability to advance in the social and academic domains. Direct Instruction – Language for Learning (DI-LL) is a highly structured intervention with empirical support in children with language delay uncomplicated by ASD. However, DI-LL has not yet been carefully studied in children with ASD. As in ABA, the DI-LL curriculum incorporates immediate reinforcement for correct responses, immediate and systematic error correction procedures, shaping, prompting, and fading. To date, there is only one small study of DI-LL in children with ASD and language delay. The purpose of this study is to test the efficacy of DI-LL in a six-month randomized clinical trial in children with ASD and moderate language delay. Eligible subjects will be randomly assigned to DI-LL plus Treatment As Usual (TAU) or TAU alone for 6 months. Children in DI-LL return for follow up at 3 and 6 months post-treatment.					
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## 1. INTRODUCTION:

Available information indicates that as many as 75% of children with autism spectrum disorder (ASD) have language delay ranging from moderate to extreme. Many interventions have been developed to address language delay including intensive treatment using applied behavior analysis (ABA). Although often effective for severe language delay (e.g., children with no language), intensive ABA intervention may not be needed for children with moderate language delay. Moderate language delay that is not treated predictably interferes with the child's ability to advance in the social and academic domains. Direct Instruction – Language for Learning (DI-LL) is a highly structured intervention with empirical support in children with language delay uncomplicated by autism spectrum disorder. However, DI-LL has not yet been applied to children with ASD. As in ABA, the DI-LL curriculum incorporates immediate reinforcement for correct responses, immediate and systematic error correction procedures, shaping, prompting, and fading. To date, there is only one small study of DI-LL in children with ASD and language delay. The purpose of this study is to test the efficacy of DI-LL in a six-month randomized trial in 100 children with ASD and moderate language delay. Eligible subjects will be randomly assigned to DI-LL plus Treatment As Usual (TAU) or TAU alone for 6 months. Children in DI-LL will return at 6 months post treatment for evaluation. Children in DI-LL will return at 6 months post treatment for evaluation. Children randomized to TAU only are offered six months of DI-LL after the randomized phase.

### KEYWORDS:

Autism Spectrum Disorder, Language Delay, Communication, Clinical Trial

## 2. OVERALL PROJECT SUMMARY:

### Statement of Work

The following Major Tasks were completed in this year of the grant:

- Randomized 76 subjects (as of 07/31/2019)
- Completed DSMP as scheduled (April, 2019)

### Changes

On March 12, 2019, we made a few changes to study personnel listed in the consent form. No other amendments over the past year.

### Personnel

In December of 2017 the Marcus Autism Center initiated a center-wide restructuring to support the Center's overall strategic goals. In this restructuring a number of positions were eliminated, including the coordinator position which Medina Bello held and a half-time DI therapist position held by Tyra Gains.

To meet the coordinating needs for DoD DI-LL, we promoted one of our DI therapists, Rebecca Kilbourne, to a coordinator position. She assumed coordinator responsibilities in late March 2018. A senior research coordinator on Dr. Scahill's clinical trials team (Nichole Evans) assumed responsibilities for recruitment. For DI therapist needs, an internal Marcus hire, Sidney Messer, assumed the half-time DI therapist role in late March 2018. She assumed a full time role

in Fall 2018. We also filled the full time DI therapist position left open by the promotion of Ms. Kilbourne.

### **Problems**

The loss of personnel and changes in recruitment practices center-wide hindered our subject accrual in 2018. For example, the former Marcus centralized recruitment and screening pipeline was reduced in scope. In response, our team had to develop a new set of approaches to recruitment. For example, we now have obtained a partial HIPAA waiver, which permits identification of potential participants via the electronic medical record. While the HIPAA waiver was under review, recruitment was on hold. The HIPAA waiver and other recruitment initiatives has paid off. Thus far in the calendar year of 2019, we have randomized 25 participants. We have several screens scheduled in August.

### **Participants**

As of July 1, 2019, parents of 127 children have consented to enroll the child into the study. Of these, 53 (41.7%) failed to meet eligibility criteria at the in-person screen. Most of the children who did not meet entry criteria scored too low on the CELF - indicating severe language delay. Eleven children scored above the CELF cut off. Two children exhibited prominent disruptive behavior problems that would predictably interfere with ability to participate in the intervention. Parents of 6(4.7%) potentially eligible subjects declined to enter. 76 subjects have been randomized. This reflects an increase of 25 subjects thus far in 2019. 49 subjects have completed the 6-month randomized trial. Attrition is 10.5% (8 of 76 randomized participants).

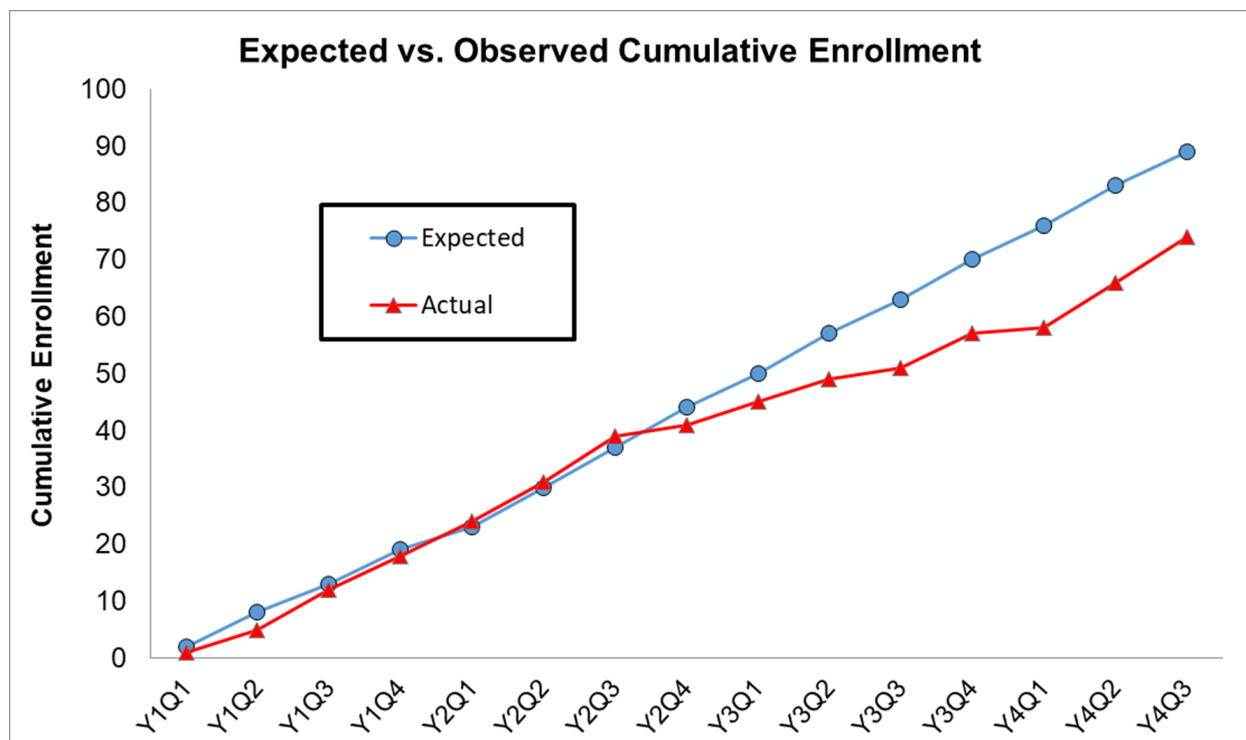
We completed a data audit on all primary and secondary outcome measures on the 57 completed subjects. Overall, less than 10% of data are missing (91.8% completion rate). Primary reason for missing data was due to subjects dropping out of study after baseline. This accounted for nearly all the missing data.

### **3. KEY RESEARCH ACCOMPLISHMENTS:**

Nothing to report

### **4. CONCLUSION:**

We have worked through the changes in personnel and mandated recruitment policy changes. Recruitment is exceeding our former pace (see Figure below drafted in June 30, 2019). Thus, despite personnel changes and changes in recruitment methods, the difference between observed and expected accrual is lower than calendar year 2018.



## 5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

- (1) Lay Press: None
- (2) Peer-Reviewed Scientific Journals: None
- (3) Invited Articles: None
- (4) Abstracts: None

- a. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.

Nothing to report

**6. INVENTIONS, PATENTS AND LICENSES:**

Nothing to report

**7. REPORTABLE OUTCOMES:**

Nothing to report

**8. OTHER ACHIEVEMENTS:**

Nothing to report

**9. REFERENCES:**

Nothing to report

**10. APPENDICES:**

Nothing to Report

**TRAINING OR FELLOWSHIP AWARDS:**

Nothing to report

**COLLABORATIVE AWARDS:**

Nothing to Report

**MARKING OF PROPRIETARY INFORMATION:**

Nothing to Report