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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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14. ABSTRACT 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. 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 autism spectrum disorder. 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 trial in 100 children with ASD and moderate language delay. Eligible subjects will be randomly assigned to DI-LL or Treatment As Usual (TAU) for 6 months.					
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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 or Treatment As Usual (TAU) for 6 months.

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 our 51st subject (as of 05/21/2018)
- Completed DSMP as scheduled (April, 2018)
- We are set to hire a 1.0 FTE DI therapist to keep pace with enrollment demands

Changes

Over the past year, the protocol has had two revisions: amendment 10 (drafted 04/02/2018); amendment 11 (drafted 06/07/2018).

Amendment 10 (in version 5.7) formalized the visit window of each post-baseline assessment visit to +/- 5 days from the target date (i.e., weeks 8, 12, 16, 24, 36, 48). We removed Caitlin Delfs, PhD as Co-Investigator of the study as she recently resigned from her position at Marcus and Emory (she continues to serve as a consultant). We clarified the time point for collecting the parent Satisfaction Questionnaire: either Week 24 or Week 48 depending on when DI LL treatment was received.

Version 5.7 also included a few changes to the Pilot study schedule of measures, i.e., we removed the DOSL and added the Satisfaction Questionnaire.

Amendment 11 (in Version 5.8) described the new recruitment methods including phone screening and removed mention of the Marcus-wide data repository. The Marcus-wide repository is no longer in place.

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 level research coordinator of Dr. Scahill's clinical trials team assumed interim coordinating responsibilities. For DI therapist needs, an internal Marcus hire, Sidney Messer, assumed the half-time DI therapist role in late March 2018. Currently, we are recruiting for a candidate to replace the full time DI therapist position left open by Ms. Kilbourne.

Problems

The loss of personnel and changes in recruitment practices center-wide hindered our subject accrual. For example, the 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 requested and we now have obtained a partial HIPAA waiver. This allows us to identify 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 are now in place and we are beginning to see positive results (we have screening visits scheduled for July 26 and August 9, 2018).

Participants

To date, parents of 85 children have consented to enroll the child into the study. Of these, 28 (32.9%) failed the in-person screen; 17 of 28 children scored too low on the CELF, 10 scored above the CELF cut off. The one other screen failure was due to prominent disruptive behavior problems that would predictably interfere with ability to participate in the intervention. Of the remaining 57, 6 potentially eligible subjects declined to enter and 51 subjects randomized. 39 subjects have completed the 6-month randomized trial. Attrition remains under 10% (4 of 51 randomized participants).

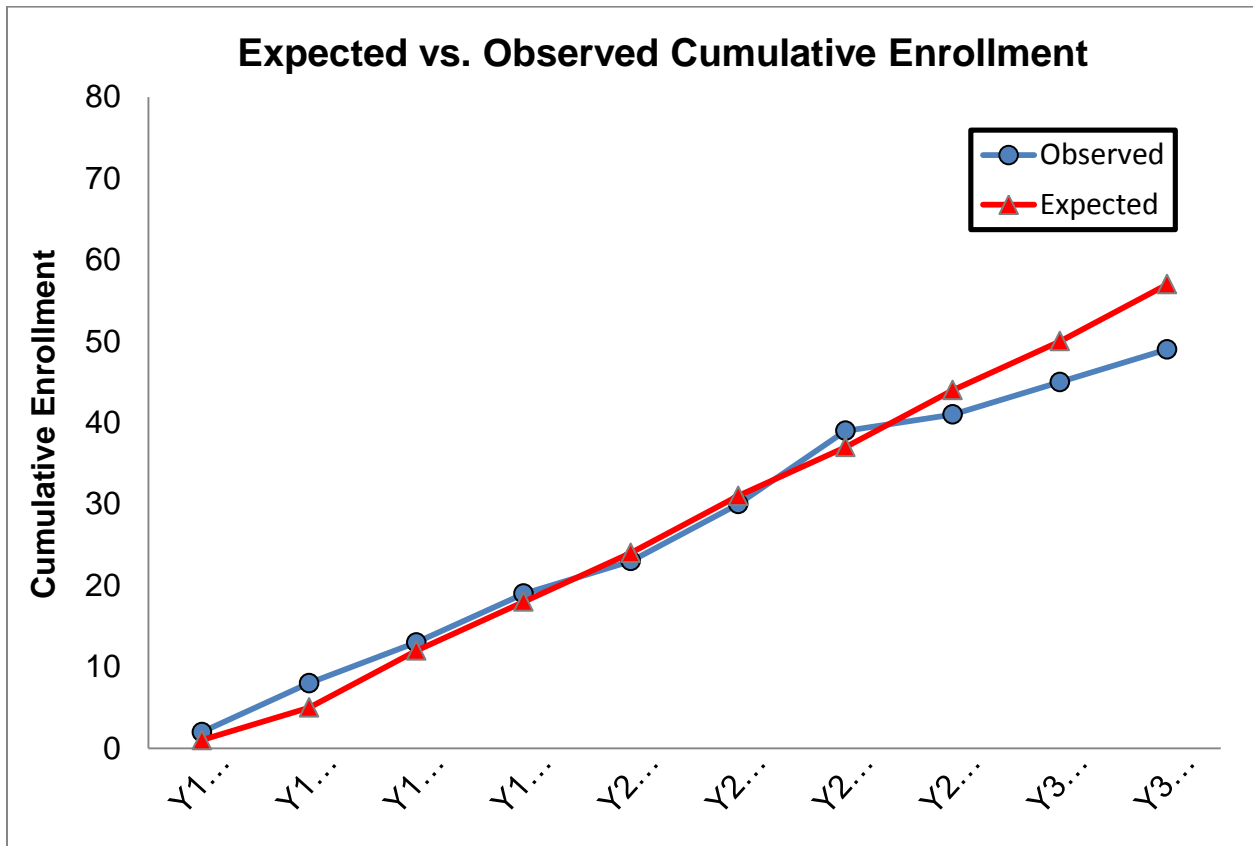
We completed an internal data audit on all primary and secondary outcome measures on the 39 completed subjects (Table 8). Less than 10% of data are missing. Primary reason for missing data was due to subjects dropping out of study after baseline. These subjects accounted for nearly all the missing data.

3. KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report

4. CONCLUSION:

We have worked through the changes in personnel and mandated recruitment policy changes. Recruitment is returning to our former pace. The new full time DI therapist will join soon (see Figure below drafted in May, 2018). Thus, despite personnel changes and changes in recruitment methods, the difference between observed and expected accrual remains small.



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