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TITLE: "Efficacy of the Direct Instruction Language for Learning (DI-LL) 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 39th subject (as of 06/29/2017)
- Completed DSMP as scheduled
- We are set to hire a 0.5 FTE DI therapist to keep pace with enrollment demands

Changes

In August, 2016, we reviewed our phone screen procedure. We undertook this review because 40% of children who appeared eligible on phone screen were not eligible on the in-person assessment because they could not meet the minimum score on the CELF-4 or CELF-P. This review led to several revisions in the phone screen in order to improve the rate of children who qualify for the study. Since we started using the revised phone screen, the rate of children who do not qualify on the in person assessment dropped to 16%.

Protocol Revisions

Protocol Version 5.5 (drafted 06/13/17) included several revisions and clarifications.

1). The requirement that participants have to be in a pre-school or elementary school program has been dropped. When we lowered the age to include 4-year-old children we soon realized that children < age 5 are in various programs from day care to structured pre-kindergarten programs. The demand that children < 5 be in an actual educational program did not make sense. For children who are in a pre-school or elementary school program, however, the requirement that the educational program is stable remains.

2). There was an inconsistency in the age span listed in the inclusion criteria and the revision described in Version 3.0 (11/03/15). In Version 3.0, we indicated our intention to revise the age range: ≥ 4 to ≤ 7 years 11 months. For reasons that are not clear, the inclusion criterion erroneously stated ≥ 4 to ≤ 7 years 6 months. This error is now corrected.

3). The criterion scores on CELF 4 and CELF P for study inclusion and exclusion has been clarified. This clarification was required because of the slight differences in the CELF-4 and the CELF-P. The floor value for CELF-4 is 40; the floor value of the CELF-P is 45. The term, *floor value* is the lowest score possible on the test. As with many other standardized tests, children with a score of 40 CELF-4 or 45 or CELF-P could actually be performing lower than the test floor – but the test is unable to measure how much lower the score should be. In such cases, the true baseline is indeterminate and result in exclusion of the subject. In some cases, however, the speech language pathologist can infer that the floor value is a true reflection of the child's performance. Because we can establish the baseline, we will include these children.

Protocol version 5.0 (drafted 10/17/2016) We sought and received IRB-approval to conduct a pilot study focusing on children who failed to qualify for the study because they scored too low on the CELF-4 or CELF-P. These children will be given an alternate language test, the Preschool Language Scale (PLS) in place of the CELF. They will be offered Direct Instruction twice a week as in the parent study. To date, no subjects have enrolled in this pilot as we have not had any subjects fail screening due to scoring too low on the CELF (since receiving IRB approval for the pilot).

The rationale for this pilot study is to gather preliminary data on children do not qualify for the randomized trial, but may benefit from Direct Instruction-Language for Learning.

Personnel

Dr. Alice Shillingsburg has accepted a position at the May Institute in Massachusetts. She will serve as a consultant to this study. We added Bethany Hansen, PhD to the protocol as a co-investigator. She will fill the role of Dr. Shillingsburg and meet with the primary caregiver at endpoint of the randomized trial (Week 24) and at the last follow up visit (Week 48) to discuss treatment planning for the child. We have asked Dr. Hansen to provide this important consultation because she is familiar with the relevant services in the community.

Problems

Since the changes in the phone screen described above, only 4 subjects have failed the in person screening. Of these, 3 subjects scored above the cut of 80 on the CELF indicating only mild language delay. We will continue to monitor our rate of screen failures. If we see additional children who fail at screening due to scoring too high on the CELF, we will revise the phone screen to reduce the rate of screen failures.

Participants

To date, parents of 65 children have consented to enroll the child into the study. Of these, 21 (32.3%) failed on the in-person screen; 12 of 21 did not qualify because they scored too low on the CELF, 7 did not qualify because they scored above the CELF cut off and the other 3 screen failed for other reasons. Of the remaining 44, 5 potentially eligible subjects declined to enter and 39 subjects randomized. 21 subjects have completed the 6-month randomized trial.

3. KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report

4. CONCLUSION:

Despite initial challenges with subjects scoring too low on the CELF-4, the addition of the CELF-P (11/30/15) and revisions to the phone screen have enabled us to keep pace with expected recruitment. Indeed, the 40% rate of screen failure dropped to 16% since August, 2016. We fully expect to randomize 50 children at the halfway point of the grant.

The addition of a 0.5 FTE DI therapist will allow us to continue our current rate of enrollment of 2-3 subjects randomized per month. This rate of enrollment should allow us to complete the study within the projected timeline.

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