

AWARD NUMBER: W81XWH-15-1-0154

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

PRINCIPAL INVESTIGATOR: Lawrence Scahill, MSN, PhD

CONTRACTING ORGANIZATION: Emory University School of Medicine, Atlanta, GA

REPORT DATE: September 2021

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE September 2021		2. REPORT TYPE FINAL		3. DATES COVERED 15JUN2015 - 14JUN2021	
4. TITLE AND SUBTITLE Efficacy of the Direct Instruction Language for Learning Program to Promote Expressive and Receptive Language in Children with Autism Spectrum Disorder				5a. CONTRACT NUMBER W81XWH-15-1-0154	
				5b. GRANT NUMBER W81XWH-15-1-0154	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) L. Scahill, MSN, PhD; R. Kilbourne, BS; A.N. Evans, BA; E-Mail: lawrence.scahill@emory.edu ; anevans@emory.edu ; rkilbou@emory.edu				5d. PROJECT NUMBER 10685862	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) EMORY UNIVERSITY 201 DOWMAN DR ATLANTA GA 30322-1007				8. PERFORMING ORGANIZATION REPORT NUMBER None	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S) eIRB	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S) None	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES Nothing to report					
14. ABSTRACT 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.					
15. SUBJECT TERMS Autism Spectrum Disorder, Language, Communication					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 12	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	6
5. Changes/Problems	8
6. Products	9
7. Participants & Other Collaborating Organizations	11
8. Special Reporting Requirements	12
9. Appendices	12

1. INTRODUCTION:

This study evaluated the efficacy of Direct Instruction Language for Learning in pre-school and young school-age children with ASD and moderate language delay. Direct Instruction Language for Learning (DI) is a highly structured, commercially available program focused on expressive and receptive language skill development in children age 4 to 7 years. Key elements of DI include immediate reinforcement for correct responses, immediate and systematic error correction, shaping (setting goals in discrete steps), prompting (clear instructions), and fading (gradual reduction in the frequency of positive reinforcement). A meta-analysis of 56 studies reported an average effect size of 0.54 for Direct Instruction Language for Language (DI) in the general population of children with language delays.¹A pilot study of DI in 25 children with ASD and language delay also provides preliminary support for efficacy. In that study, DI was delivered individually twice a week for 13 weeks. Children attended 86% of sessions and independently rated therapist fidelity was at 95% (range 73%–100%). Here we report on the efficacy of DI when added to treatment as usual compared to treatment as usual alone. The aim of the study was to evaluate the efficacy of DI in 83 children with ASD and moderate language delay when delivered by trained non-specialists in a clinic setting. Children were randomly assigned to Treatment as Usual (TAU) + DI or TAU only for 6 months.

2.KEYWORDS:

Autism spectrum disorder, language delay, structured intervention

3. ACCOMPLISHMENTS:

The study is completed, the primary paper is under review at the Journal of the American Academy of Child and Adolescent Psychiatry.

What were the major goals of the project?

To evaluate the efficacy of DI when added to TAU in preschool age children with ASD and moderate language delay. The primary outcome was the change on the Clinical Evaluation of Evaluation Language Fundamentals (CELF) administered by a speech pathologist who was blind to treatment assignment.

The key secondary outcome was the Improvement item on the Clinical Global Impression assessed by a clinician who was blind to treatment assignment. We also examined the rate of children in each group that achieved the minimal clinically important difference of 5 or more points on the on the CELF.

What was accomplished under these goals?

Children were randomly assigned to continue treatment as usual (TAU) only or DI+TAU for six months. TAU included any combination of speech therapy in school or in the community that was stable for at least a month before study entry with no planned changes for six months. Following the 6-month randomized phase, children in TAU were offered 6 months of treatment with DI. Children randomly assigned to DI+TAU were invited to return for follow-up at Weeks 36 and 48. The long-term effects of DI will be presented in a separate report.

Two hundred sixty nine children were screened by telephone. Of these, 137 participated in the formal clinical assessment; 26 were too low on the CELF and 15 were > 80 on the CELF. Eighty-three participants (71 boys, 12 girls) were randomized. Of these, 10 participants (5 per group) dropped out prior to Week 24. Due to unanticipated family circumstance, one participant had an early termination CELF assessment at Week 21. One participant was unable to return at endpoint due to COVID-19 restrictions.

At Week 24, children in DI + TAU showed a 4.8-point (8.1%) increase in the standard score on the CELF-4 or CELF-P compared to 2.3 points (4.1%) in TAU. The adjusted mean difference at Week 24 was 2.55; 95% CI (-0.85, 5.95), p=0.14; effect size 0.25 (see Table 3). When adjusted for IQ as a covariate in the mixed model, the adjusted mean difference at Week 24 was 3.5 (95% CI: 0.14, 6.84; p = 0.04; effect size = 0.33).

Table 3. CELF standard scores conditioned on baseline scores and adjusted for IQ

	DI N = 42		TAU N = 41		Mean Difference at Wk 24	95% CI	P-value (ES)
	Baseline N = 42	Wk 24 N = 36	Baseline N = 41	Wk 24 N = 36			
CELF scores conditioned on baseline	59.2 (10.2)	64.0 (12.0)	55.7 (9.2)	58.0 (10.7)	2.55	(-0.85, 5.95)	0.14 (0.25)
CELF Adjusted for IQ	59.2 (7.0)	64.3 (8.6)	55.7 (8.3)	57.7 (10.3)	3.49	(0.14, 6.84)	0.04 (0.33)

On the CGI-I, the treatment blind IE rated Much Improved or Very Much Improved in 19% of children in DI+TAU and 4.9% in TAU at Week 12. By Week 24, 54.8% (23/42) of DI+TAU participants were classified with positive response compared to 22.0% (9/41) in TAU (Chi square = 9.4; p=0.002) (number needed to treat = 3.0).

Exploratory Analyses. In children with complete CELF data (n=72), the change from baseline showed a wide range from -12 to +19 in DI + TAU and from -16 to +17 in TAU. Five of 36 participants (13.9%) in DI + TAU had lower scores at Week 24 compared 41.7% (15 of 36) in TAU (Chi square 8.65, p=0.003). On the anchor-based, within-participant minimal clinically important difference (MCID), 20 of 36 (55.5%) of DI+TAU participants achieved 5 points or greater on the CELF compared to 12 of 36 (33.3%) in TAU (Chi square = 3.6; p=0.06) (number needed to treat = 4.5). Collapsing over both treatment groups, 28 of 52 children (53.8%) with a pre-treatment CELF score > 50 achieved the MCID of 5 points compared to 4 of 20 (16.7%) with a pre-treatment score ≤ 50 (Fisher exact p value =0.02; odds ratio = 4.7).

There were 255 adverse events reported on 74 participants during the 24-week trial with no group differences. Table 4 lists the adverse events that occurred in ≥ 5% of participants in either treatment group. There were no serious adverse events.

What opportunities for training and professional development has the project provided?

We had a psychology graduate intern from Mercer University for one year.

How were the results disseminated to communities of interest?

At DOD request, we provided a summary for a DOD-sponsored dissemination purpose. The PI has given two grand rounds presentations. The Marcus Newsletter included a summary of the results. The primary paper has been accepted by the J of American Academy of Child and Adolescent Psychiatry.

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to Report

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

This is the first randomized trial of DI in ASD to use blinded assessments of DI + TAU versus TAU alone. We expect to publish one or two more papers.

What was the impact on other disciplines?

Our study shows that about half of the children in DI + TAU had positive effect. DI can be delivered by a wide range of practitioners (i.e, beyond speech pathologists).

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Moderate language delay affects as many as 50% of children with ASD. Moderate language delay impairs social communication and learning. DI offers an option for intervention.

5. CHANGES/PROBLEMS:

Nothing to Report

Changes in approach and reasons for change

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to Report

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Journal publications.

The primary paper has been accepted at the J of American Academy of Child and Adolescent Psychiatry.

Books or other non-periodical, one-time publications.

None

Other publications, conference papers and presentations.

Grand Rounds: Marcus Autism Center
(10/2020)
Grand Rounds Stanford University 1/2021

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Scahill, L., Shillingsburg, M.A., Ousley, O., Pileggi, M., Kilbourne, R., Buckley, D., Gillespie, S. McCracken, C.E. (in press). A randomized trial of Direct Instruction Language for Learning in Children with Autism Spectrum Disorder. *Journal of the American Academy of Child and Adolescent Psychiatry*

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

No change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Marcus Foundation (Atlanta, GA): financial support

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

Primary paper is under review.