AWARD NUMBER: W81XWH-19-1-0293

TITLE: Assessing the Effectiveness of a Low-Cost, Evidence-Based, Naturalistic Developmental Behavioral Intervention (NDBI) in IDEA Part C Early Intervention Settings

PRINCIPAL INVESTIGATOR: Wendy Stone

CONTRACTING ORGANIZATION: University of Washington

REPORT DATE: AUGUST 2023

TYPE OF REPORT: Annual Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
AUGUUST 2023	Annual Report	15JUL2022 - 14JUL2023

4. TITLE AND SUBTITLE

Assessing the Effectiveness of a Low-Cost, Evidence-Based, Naturalistic Developmental Behavioral Intervention (NDBI) in IDEA Part C Early Intervention Settings

5a. CONTRACT NUMBER
W81XWH-19-1-0293

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Dr. Wendy Stone

E-Mail: stonew@uw.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Washington
Department of Psychology
Box 357920
Center on Human Development
and Disability
Seattle, WA 98195-7920

8. PERFORMING ORGANIZATION REPORT NUMBER

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)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Numerous research studies have indicated that participation in early, specialized intervention leads to significant improvements in social, language, cognitive, and behavioral functioning for young children with autism spectrum disorder (ASD). However, very few ASD-specialized interventions have been adapted for use in community-based settings, where they may be more accessible. The purpose of this study is to assess the effectiveness of Reciprocal Imitation Training (RIT)--an evidence-based, ASD-specialized intervention–for use by community providers working in publicly funded (IDEA Part C) Early Intervention (EI) programs serving children from birth to 3 years. We are using a hybrid effectiveness-implementation design to examine both the implementation of RIT by EI providers as well as child and parent outcomes associated with its use. We will collect data from EI providers about the acceptability and feasibility of using RIT, as well as the extent to which it is used and sustained over time. This project has the potential to enable more children with ASD to receive evidence-based, specialized intervention during the birth-to-three years, when it is likely to have the greatest impact.

15. SUBJECT TERMS autism spectrum disorder; Reciprocal Imitation Training

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
U	U	U	UU	13	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

REPORT OUTLINE – Y4 Annual

1. INTRODUCTION (Original Abstract)

Numerous research studies have indicated that participation in early, specialized intervention leads to significant improvements in social, language, cognitive, and behavioral functioning for young children with autism spectrum disorder (ASD). However, very few ASD-specialized interventions have been adapted for use in community-based settings, where they may reach a broader segment of the population. The purpose of this study is to assess the effectiveness of Reciprocal Imitation Training (RIT) -- an evidence-based, ASD-specialized intervention – for use by community providers working in publicly funded (IDEA Part C) Early Intervention (EI) programs serving children from birth to 3 years. We are using a hybrid effectiveness-implementation design to examine both the implementation of RIT by EI providers as well as child and parent outcomes associated with its use. We will collect data from EI providers about the acceptability and feasibility of using RIT, as well as the extent to which it is used and sustained over time. To examine providers' (*n*= 80) *implementation* of RIT, an RCT design will be used; providers will be randomized to either a one-day RIT training workshop or to a control condition in which providers receive a two-hour webinar in helping caregivers increase their child's participation in everyday home routines. To examine the *effectiveness* of RIT for children and parents, we will compare RIT (*n*=80) and Control (*n*=80) Groups. This project has the potential to enable more children with ASD to receive evidence-based, specialized intervention during the birth-to-three years, when it is likely to have the greatest impact. Importantly, if RIT is found to be effective for use by EI providers, we have the potential to disseminate this intervention within the existing infrastructure of the EI system to make it available to families across the U.S. **NOTE:** Due to pandemic-related challenges that impeded provider recruitment, in August 2022 the target sample size was reduced to 30 providers per group (60 total).

2. KEYWORDS

Early Intervention; Autism Spectrum Disorder, Hybrid Effectiveness/Implementation Trial, Reciprocal Imitation Training (RIT), Treatment Fidelity, Community-based Research, Motor Imitation, Social Communication

3. ACCOMPLISHMENTS

3.1 What were the major goals of the project?

The major goals for this project during Year 4 were to: (1) Complete EI Provider enrollment, conduct the provider training workshops, collect and summarize the provider T1-T5 survey data, and collect the provider videos of EI sessions with families; (2) Complete Family enrollment, conduct the virtual child assessments, collect and summarize the T1-T3 survey data from caregivers, and collect weekly dosage log data from families in the RIT group; (3) Prepare the videotape data for coding (e.g., segmenting), and begin coding the videos of child assessments, caregiver-child interactions, and provider use of use of RIT strategies; and (4) Conduct preliminary data analyses with the goal of developing manuscript submissions.

3.2. What was accomplished under these goals?

Overview

We have continued to make considerable progress during the past year, despite the challenges and delays wrought by the COVID-19 pandemic. As noted previously, we were forced to radically adapt our research design and data collection methods, and did not receive HRPO approval to re-start the project until April 2021. This delay resulted in a substantially altered timeline for our activities, especially with respect to participant recruitment. The pandemic also severely affected the operations of the EI programs from which we recruited both providers and families. We are grateful to have been awarded a no-cost extension, which will enable us to continue to collect family and provider surveys, complete child assessments, and continue video coding and data analyses.

3.2.1 Continuing to enroll and collect data from EI providers

We have completed EI provider enrollment (n=56) and provider training workshops, and are continuing to collect provider surveys. To date, we have collected 56/56 Time 1 surveys (100%), 50/53 Time 2 surveys (94%), 47/52 Time 3 surveys (90%), 45/51 Time 4 surveys (98%) and 20/21 Time 5 surveys from providers (95%). Fifteen of the 56 enrolled providers have now completed all time points and have 'graduated' from the study (6 in the RIT group and 9 in the Routines group).

Time 3 survey responses revealed that 96% of providers in the RIT group have used RIT with children in their caseloads, and 88% in the Routines group have used the Routines workshop strategies with families. In addition, preliminary results indicate that providers in the RIT group reported increased confidence (from T1 to T3) in identifying treatment goals, providing direct intervention, and coaching families of children in their caseloads with autism (*p*s range from .003 - .018). In addition, they reported increased use of the strategies of modeling language and imitating the child's actions with toys and body movements (*p*s range from .007 - .034), which are core elements of RIT.

Each provider was asked to videotape a typical EI session with two of their enrolled families. We have now received 41 videos of EI sessions, 17 from the RIT group and 24 from the Routines group. 21 providers submitted one video, 7 providers submitted 2 videos, and 2 providers submitted 3 videos. This is a lower number than expected, and the quality and content of the videos are quite variable. Nonetheless, we are currently developing a coding system for the recordings, to determine whether there are group differences in providers' use of RIT strategies.

3.2.2 Continuing to enroll families and collect data from caregivers

We enrolled families in the study through 2/28/2023. We made the decision to cease family recruitment in order to minimize the number of families who were not projected to complete their final surveys prior to the study end date. Our strategies of broadening the age range of children and conducting a random drawing for providers who refer eligible families to the study proved very helpful in increasing our family enrollment. However, only 66% of the providers referred eligible caregivers to the study.

For the RIT group, we have conducted 19/19 Time 1 (100%), 17/19 Time 2 (89%), and 7/11 Time 3 (64%) virtual child assessments, and have collected 19/19 Time 1 (100%), 18/19 Time 2 (95%), and 6/11 Time 3 (55%) caregiver surveys. In addition, we have collected a total of 268 weekly RIT dosage logs from 18 families in the RIT group.

For the Routines group, we have conducted 24/24 Time 1 (100%), 23/24 Time 2 (96%), and 17/19 Time 3 (71%) virtual child assessments, and have collected 24/24 Time 1 (100%), 22/24 Time 2 (92%), and 14/19 Time 3 (84%) caregiver surveys.

Importantly, the randomization process resulted in similar demographic characteristics across the two groups. Caregivers in both groups reported comparable levels of parenting stress and efficacy and comparable levels of their child's social-communication skills at Time 1. In addition, demographic data suggest that study participants were diverse in terms of ethnicity and receipt of public assistance.

Final Child Demographics:

Age: Mean = 26 months (range: 16-31 months)
Sex: Male = 35 (76%); Female = 11 (24%)
Race: White: 36 (78%); Black/African American: 3 (7%); Native American or Other Pacific Islander: 1 (2%); More than one race: 2 (5%); Unknown: 4 (9%).
Ethnicity: Hispanic/Latino: 18 (39%); Unknown: 2 (4%).
Percent of children/families receiving public assistance: 54%

Final Caregiver Demographics:

Age: Mean = 31 years (range: 19-41 years)
Gender: Female = 44 (96%); Male = 2 (4%)
Race: White: 35 (76%); Black/African American: 3 (7%); Native American or Other Pacific Islander: 1 (2%); Unknown: 3 (6%); Other: 6%.
Ethnicity: Hispanic/Latino: 11 (24%); Non-Hispanic/Latino: (76%).

3.2.3. Continuing and expanding the processes of video coding and data analysis

There are several steps involved in the video coding process: *segmenting the videos* so that coders are not influenced by child behaviors that occur during other videotaped parts of the assessment; *identifying a coding system* to capture the behavior of interest, and *training coders* to identify both examples and non-examples of the behavior. As part of the training, coders (who are blinded to the treatment group and measurement timepoint) must meet set standards for interrater reliability before they begin independent coding. Once independent coding begins, reliability is periodically checked to monitor and correct any coding drift.

Segmenting: We have made great progress in segmenting videos during the reporting period. To date we have segmented 108 videos, comprising 95% from Time 1, 85% from T2, and 88% from Time 3.

Identifying a coding system: We are currently working on 3 coding systems to capture: providers' use of RIT strategies; children's use of intentional communication; and

caregivers' use of RIT. These coding systems are at and these are at various stages of development. First, we are in the process of creating a system for coding the EI providers' use of RIT strategies from the videos they submitted. Second, we are coding Intentional communication using an established system (Weighted Frequency of Intentional Communication (Yoder, Stone, Walden & Malesa, 2009) and we are in the early stages of training coders. Third, we are currently coding caregiver's use of RIT strategies during free play, and we have successfully coded 10 T1, 14 T2, and 4 T3 videos to date.

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

This project has continued to provide numerous training and professional development activities for research staff at all levels. Each year, Dr. Stone has taught a seminar for graduate and undergraduate students during all 3 quarters (i.e., Fall, Winter, Spring) that involves discussion of research activities, methodological approaches, and the latest findings in topic areas related to this project. In addition, undergraduate research assistants and honors students, postbaccalaureate research assistants, graduate students, and our postdoctoral fellow have participated in weekly meetings focused on grant-related activities. Our trainees also have the opportunity to learn and conduct assessments and serve as co-trainers for the workshops, and often go on to graduate programs in related fields.

3.4 How were the results disseminated to communities of interest?

Nothing to report.

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

During our no-cost extension year, we will: (1) continue to collect provider and family survey data; (2) continue to conduct virtual child assessments; (3) continue to code videos of child assessments; and (4) analyze final study data and prepare manuscripts for publication.

4. IMPACT

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

Part C Early Intervention providers come from varied professional disciplines and work within a generalist model of service provision. Provider backgrounds include speech/language pathology, early childhood special education, occupational therapy, physical therapy, and others. Providers in the RIT group learned new evidence-based strategies for interacting with children with autism, improving social communication in children with autism, and coaching caregivers in the independent use of these strategies with their children at home. EI providers in the Routines group learned a systematic approach for helping caregivers improve their child's participation and engagement in everyday home routines.

4.2. What was the impact on other disciplines?

N/A.

4.3. What was the impact on technology transfer?

N/A.

4.4. What was the impact on society beyond science and technology?

Our ultimate objective of this research is to improve the lives of children with autism and their families. In this study we have introduced evidence-based strategies that are inexpensive and can be used by providers as well as families to promote child development and enhance the capacity of caregivers to understand and interact with their children. We do not yet have sufficient data from caregivers regarding the impact of these interventions on their everyday activities at home, or the impact on their children's development, but will continue collecting these data during our No-Cost Extension year.

5. CHANGES/PROBLEMS

As noted previously, we have faced numerous challenges in conducting this research project, most of which are related to the COVID-19 pandemic. Our initial challenge was the need to completely revamp our study design and data collection methods to accommodate the unprecedented use of virtual-only tools. We did not receive HRPO approval to re-start the project until April 2021, resulting in a substantially shortened timeline for our activities, especially with respect to participant recruitment. The pandemic also severely affected the operations of the Part C EI programs from which we recruited both providers and families; these challenges included reductions in staffing, larger caseloads for the remaining providers, and shorter EI sessions with families to accommodate their increased caseloads.

We are grateful to have been awarded a no-cost extension, which will enable us to continue to collect family and provider surveys, complete child assessments, and continue data analyses.

6. PRODUCTS

6.1. Publications, conference papers, and presentations

Nothing to report yet.

6.2. Website(s) or other Internet site(s)

Nothing to report.

6.3. Technologies or techniques

Nothing to report.

6.4. Inventions, patent applications, and/or licenses

Nothing to report.

6.5. Other Products

Nothing to report.

7.1. What individuals have worked on the project?

Name:	*Wendy Stone*
Project Role:	*Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	0000-0002-8546-7536
Nearest person month worked:	*0.76 month (for year 4)*
Contribution to Project:	*Dr. Stone directs the course of study and oversees all study activities.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Jill Locke*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	0000-0003-1445-8509
Nearest person month worked:	*0.6 month (for year 4)*
Contribution to Project:	*Dr. Locke provides consultation on the implementation aspects of the study.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Kevin King*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	*0000-0001-8358-9946*
Nearest person month worked:	*0.02 month (for year 4)*
Contribution to Project:	*Dr. King has expertise in mixed method statistical approaches and methodology. He is conducting the randomization process and provides statistical consultation for all analyses.*
Funding Support:	

Name:	*Karen Bearss*
Project Role:	*Clinician*
Researcher Identifier (e.g. ORCID ID):	0000-0002-1559-146X
Nearest person month worked:	*0.6 month ((for year 4)*
Contribution to Project:	*Dr. Bearss provides consultation on behavioral assessments.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Daina Tagavi*
Project Role:	*Postdoctoral Scholar*
Researcher Identifier (e.g. ORCID ID):	0000-0002-0521-7474
Nearest person month worked:	*3.1 months ((for year 4)*

Contribution to Project:	*Dr. Tagavi oversees and conducts behavioral assessments and provides training for the research assistants and graduate students.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Carol Schubert*
Project Role:	*Research Coordinator*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*0.12 month ((for year 4)*
Contribution to Project:	*Ms. Schubert manages the study budget and assists with study reports.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*John Hershberger*
Project Role:	*Research Study Coordinator*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*11.4 months (for year 4)*
Contribution to Project:	*Mr. Hershberger prepares IRB modifications, enrolls providers, coordinates trainings, conducts data analyses, compensates study participants, and monitors data collection applications (REDCap and Twilio).*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Clara Herrera*

Project Role:	*Research Study Assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*8.9 months (for year 4)*
Contribution to Project:	*Ms. Herrera assists with interactions with Spanish-speaking providers and families, and assists in conducting child assessments.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Carly Perryman*
Project Role:	*Research Study Assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*0.9 month (for year 4)*
Contribution to Project:	*Ms. Perryman schedules and conducts behavioral assessments with families, helps maintain the REDCap caregiver database, helps train new staff, and coordinates video editing and coding.*
Funding Support:	*W81XWH-19-1-0293*

Name:	*Dana Parkin*
Project Role:	*Student Research Assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*

Nearest person month worked:	*0.1 month (for year 4)*
Contribution to Project:	*Dana assists with the behavioral coding of study videos and with preparing reports for participating families.*
Funding Support:	*W81XWH-19-1-0293*

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

Wendy Stone: Dr. Stone has one new active award.

Title: *Co-Developing and Piloting Culturally-Responsive Informational Materials about Autism for Families of Young Children: Employing a Train-the-Trainer Implementation Model within a Nonprofit Setting*
Project Number: 3 UL1 TR 002319-07S1
PI: Stone, W.
Funding Source: University of Washington/NIH
Project Period: 03/2022 – 02/2024
Effort: 1.2 calendar months

Jill Locke: No change.

Kevin King: No change.

7.3. What other organizations were involved as partners?

The Part C Early Intervention programs with whom we worked.

8. SPECIAL REPORTING REQUIREMENTS

8.1. Collaborative Awards

Not applicable.

8.2. Quad Charts

Attached.

9. APPENDICES

There are no appendices.