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

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CONTRACTING ORGANIZATION: University of Washington

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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. The major accomplishments for this project during Year 2 included: (1) developing revisions to the research protocol due to COVID-19 related constraints and receiving HRPO approval; (2) developing a technology package for in-home tele-assessments; (3) adapting the RIT training protocol for virtual presentations; (4) designing and receiving feedback on a daily routines workshop for the providers in the control group; (5) testing potential apps for treatment tracking; and (6) re-engaging, recruiting, and enrolling providers. While we have made considerable progress in key areas, we did not receive approval from HRPO until 4/15/21.								
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REPORT OUTLINE

1. INTRODUCTION

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, with providers randomized to either receive an RIT training workshop at the beginning of the study or to a control group, which will receive training in a child routines webinar. 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.

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 2 included: (1) modifying the study protocol in light of the pandemic; (2) engaging and recruiting EI providers; (3) beginning data collection with both EI providers and families; and (4) conducting Wave 1 of the RIT training workshops.

3.2. What was accomplished under these goals?

Overview

The major accomplishments for this project during Year 2 included: (1) developing revisions to the research protocol due to COVID-19 related constraints and receiving

HRPO approval; (2) developing a technology package for in-home tele-assessments; (3) adapting the RIT training protocol for virtual presentations; (4) designing and receiving feedback on a daily routines workshop for the providers in the control group; (5) testing potential apps for treatment tracking; and (6) re-engaging, recruiting, and enrolling providers. While we have made considerable progress in key areas, we did not receive approval from HRPO until 4/15/21.

3.2.1. Revising the research protocol and IRB approval

The pandemic, need for social distancing, and continuous new COVID-19 outbreaks created the need for us to adapt our research design and data collection methods. Because we can no longer have face-to-face clinic visits with families to collect data on parent-child interactions and child gains in social communication, we have adapted some virtual assessments (parent-implemented with coaching) that will provide us with the data we need and have identified ways to incentivize providers for their participation (i.e., earlier RIT workshops; daily routines workshop for control group). After approval from our Program Officer, Stan Niu, the modifications were submitted to the UW IRB on 1/4/21 and approved on 2/4/21. We then compiled the materials for resubmission to the HRPO and updating the SOW timeline on 3/9/21. These modifications were then approved on 4/16/21.

3.2.2. Developing the tech package for at-home tele-assessments

To transition to tele-assessments, we have been developing a technology package to deliver to families' homes prior to the assessment. To this end, we tested several recording devices in various configurations to determine which tech package would maximize quality of camera views and videos, while also remaining feasible for parents to set up. The configurations were tested in the homes of 5 different research staff in an effort to assess the quality of the video, the feasibility of transport, and the challenges that might be encountered in the homes of study participants. Also, two detailed set-up guides were developed for use by families and research staff. Overall, two systems were tested by research staff and the final selected system is developed by Ubiquiti, which makes state-of-the art, portable video streaming equipment. We conducted the first pilot assessment with a volunteer family using this tech package and the updated protocol in July 2021, with more pilot families scheduled in August 2021.

3.2.3. Refining the RIT training and consultation curriculum

Under the direction of Dr. Stone, the team continued to adapt existing RIT materials to support EI providers in coaching parents in RIT, both in-person and over telehealth. We also leveraged other ongoing studies, including focus groups and surveys with providers, to generate insights regarding challenges to parent coaching via telehealth and further refined the virtual workshop and supporting materials (slides, video examples, interactive exercises).

3.2.4. Developing and piloting the Daily Routines webinar

To promote and incentivize their participation in the study, we developed a webinar for the control group that focuses on helping providers coach parents on how to improve their child's skills within the context of their everyday home routines (snacktime, bedtime, bathtime, and family playtime). As part of this process, PI Stone has worked with a graduate student, Alice Bravo, to translate a web-based webinar (developed by herself and colleagues) into a virtual format. This process has included presenting the workshop for feedback and content editing to a seminar including Dr. Karen Bearss, graduate students, and research staff. PI Stone piloted the approximately 1-hour workshop webinar to 9 interested community providers from a local EI program on 5/27/21. Upon completion of the webinar, all 9 participants completed an evaluation form, providing valuable feedback which has led to further refinement of the webinar, the development of an online video library, and creation of a workbook to facilitate parent coaching, which is also being translated into Spanish.

3.2.5. Reviewing and testing smartphone apps for treatment tracking

We have researched several smartphone applications and services that support automated daily surveys for treatment tracking with REDCap Mobile. This process has included technical demos of apps and communication with UW's REDCap administrative team to learn more about REDCap Mobile's capabilities. We have decided to use the Twilio app and are integrating it with REDCap in order to send weekly survey invitations to caregivers via SMS messaging. Key factors considered in our decision-making included ease of use and accessibility for study participants, ease of programming surveys, support of push notifications, data security, HIPAA compliance, and cost.

3.2.6. Engaging, recruiting, and enrolling EI providers and beginning T1 data collection

Informational webinars for EI providers were conducted during Summer 2021, and a link to the online consent form was sent to enable interested individuals to provide informed consent and enroll, and then be automatically directed to their first survey on REDCap. Enrollment has slowed down due to the new demands of the pandemic on the Part C system. Specifically, providers have been pivoting at a rapid pace to begin offering in-person services again, while also maintaining teleservices. As one agency director summarized, "My staff are trying to just keep their heads above water...straddling virtual and in-person services, bringing back classes in Sept [2021], trying to keep up with all the ever-changing processes and procedures around Covid."

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

During Fall 2020 and Winter and Spring 2021, Dr. Stone taught seminars for graduate students that involve discussion of research activities, methodological approaches, and the latest findings in topic areas related to the current study. Graduate students have also been closely involved in updating the RIT training content and developing the Routines webinar as they prepare to be co-trainers for the actual workshops.

3.3.1. How were the results disseminated to communities of interest?

Nothing to report.

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

We plan to: (1) finalize revisions to the daily routines workshop webinar; (2) continue EI provider enrollment; (3) randomize EI providers to RIT training and Control group with webinar; and (4) begin scheduling training workshops.

4. IMPACT

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

Nothing to report.

4.2. What was the impact on other disciplines?

Nothing to report.

4.3. What was the impact on technology transfer?

Nothing to report.

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

Nothing to report.

5. CHANGES/PROBLEMS

We have experienced delays in initiating provider enrollment and data collection due to the constraints incurred by COVID-19 social distancing and shelter-at-home policies, and decreased provider interest related to current demands to shift back to some in-person services. However, as mentioned above, we have adapted our protocol to address these issues, received HRPO approval, and have been re-engaging providers.

6. PRODUCTS

6.1. Publications, conference papers, and presentations

Nothing to report.

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. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

7.1. 7.1. What individuals have worked on the project?

Name:	<i>Wendy Stone</i>
Project Role:	<i>Principal Investigator</i>
Researcher Identifier (e.g. ORCID ID):	0000-0002-8546-7536
Nearest person month worked:	<i>0.30 month</i>
Contribution to Project:	<i>Dr. Stone has been overseeing all study activities and directing the course of study.</i>
Funding Support:	

Name:	<i>Lisa Ibañez</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	0000-0002-7084-3375
Nearest person month worked:	<i>1.98 months</i>
Contribution to Project:	<i>Dr. Ibañez has been overseeing all study activities and providing support for the direction of the study.</i>
Funding Support:	

Name:	<i>Jill Locke</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	0000-0003-1445-8509
Nearest person month worked:	<i>0.18 month</i>
Contribution to Project:	<i>Dr. Locke has been providing consultation on the implementation aspects of the study.</i>
Funding Support:	

Name:	<i>Karen Bearss</i>
Project Role:	<i>Clinician</i>
Researcher Identifier (e.g. ORCID ID):	0000-0002-1559-146X
Nearest person month worked:	<i>0.16 month</i>
Contribution to Project:	<i>Dr. Bearss has been consulting on issues related to the behavioral assessments and their virtual adaptation and providing feedback on the daily routines workshop.</i>
Funding Support:	

Name:	<i>Kevin King</i>
Project Role:	<i>Co-Investigator</i>
Researcher Identifier (e.g. ORCID ID):	0000-0001-8358-9946
Nearest person month worked:	<i>0.02 month</i>

Contribution to Project:	<i>Dr. King has expertise in mixed method statistical approaches and methodology. He provides statistical consultation for all analyses and will conduct the randomization process.</i>
Funding Support:	

Name:	<i>Sabine Scott</i>
Project Role:	<i>Research Study Assistant</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>1.50 months</i>
Contribution to Project:	<i>Ms. Scott has been preparing the IRB modification, testing the tech package for tele-assessments, and reviewing the RIT training materials.</i>
Funding Support:	

Name:	<i>Pascale Carpentier</i>
Project Role:	<i>Research Study Assistant</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>0.75 month</i>
Contribution to Project:	<i>Ms. Carpentier has helped with testing the tech package and the review of all Spanish translations and review of Spanish surveys in database.</i>
Funding Support:	

Name:	<i>Taylor Kalmus</i>
Project Role:	<i>Research Study Assistant</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>0.91 month</i>
Contribution to Project:	<i>Ms. Kalmus has been trained on the behavioral assessments and has helped develop the tech package for tele-assessments.</i>
Funding Support:	

Name:	<i>John Hershberger</i>
Project Role:	<i>Research Study Coordinator</i>
Researcher Identifier (e.g. ORCID ID):	<i>N/A</i>
Nearest person month worked:	<i>2.25 months</i>
Contribution to Project:	<i>Mr. Hershberger has been preparing the IRB modification, testing tech for assessments, and testing apps for treatment tracking.</i>
Funding Support:	

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?

Nothing to report.

7.3. What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

8.1. Collaborative Awards

Not applicable.

8.2. Quad Charts

Attached.

9. APPENDICES

There are no appendices.