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Assessing the Effectiveness of a Low-Cost, Evidence-Based, Naturalistic Developmental 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. To examine providers' (*n*=48) *implementation* of RIT, an interrupted time-series design will be used, with the RIT training workshops representing the "interruption." To examine the *effectiveness* of RIT for children and parents, we will employ a separate samples pre-test and post-test design that will compare Pre-RIT (*n*=48) and Post-RIT (*n*=48) Cohorts. 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 the first Year 1 included: (1) finalizing the research protocol and receiving IRB approval; (2) receiving HRPO approval; (3) developing and testing our online database; (4) hiring and training new staff; (5) translating materials into Spanish to be able to recruit Spanish speaking families; (6) creating Clinicaltrials.gov study profile; (7) receiving training on novel research techniques to improve provider/parent engagement and experience; (8) engaging with stakeholders and EI programs for study initiation; and (9) enrolling EI providers and beginning T1 data collection with EI providers.

15. SUBJECT TERMS

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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*= 48) *implementation* of RIT, an interrupted time-series design will be used, with the RIT training workshops representing the "interruption." To examine the *effectiveness* of RIT for children and parents, we will employ a separate samples pre-test and post-test design that will compare Pre-RIT (*n*=48) and Post-RIT (*n*=48) Cohorts. 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 the first Year 1 included: (1) refining and finalizing the research protocol; (2) receiving IRB approval; (3) receiving HRPO approval; (4) hiring and training new staff; (5) engaging with stakeholders and EI programs for study initiation; (6) developing and testing our online database; (7) registering study on Clinicaltrials.gov; (8) enrolling EI providers and families; (9) beginning T1 data collection with both EI providers and families.

3.2. What was accomplished under these goals?

Overview

The major accomplishments for this project during the first Year 1 included: (1) finalizing the research protocol and receiving IRB approval; (2) receiving HRPO approval; (3) developing and testing our online database; (4) hiring and training new staff; (5) translating materials into Spanish to be able to recruit Spanish speaking families; (6) creating Clinicaltrials.gov study profile; (7) receiving training on novel research techniques to improve provider/parent engagement and experience; (8) engaging with stakeholders and EI programs for study initiation; and (9) enrolling EI providers and beginning T1 data collection with EI providers. While we have made considerable progress in key areas, we were not able to initiate any recruitment- or data collection-related tasks with families because we did not receive final HRPO approval until 3/20/20 and since that time have had to make adjustments due to COVID-19 restrictions, which have persisted through the time of this report.

3.2.1. Finalizing the research protocol and receiving IRB approval

Our research team finalized the research protocol, which included streamlining the consenting process, reviewing all assessments and surveys, and developing recruitment materials. We developed methods for facilitating enrollment and consenting participants online using REDCap, which will minimize the delays often associated with mailing paper consent forms. All surveys and behavioral assessments were reviewed for content, scoring/coding systems, and duration for completion to ensure that participants are not overburdened. Recruitment materials were developed both for Early Intervention (EI) providers and potential families. For EI providers, we created 1-page handouts that briefly and clearly define the key study activities and potential benefits families and for themselves. We also created a flyer and a permission-to-contact form that EI providers can distribute to families who may be interested in participating. These materials, which are similar to those we have used successfully in previous studies, describe eligibility and the key activities and benefits associated with participation. To facilitate study recognition and engagement for potential participants and stakeholders, we developed a name (i.e., the “Sprout Study”), a logo, and a study-specific email address (i.e., sproutstudy@uw.edu). We obtained initial IRB approval from UW on 11/7/19.

Given the impact of the pandemic on in-person interactions, we are modifying the protocol for research visits with families so that they may be conducted “virtually” via secure, telehealth software.

3.2.2 Received Approval from HRPO

After obtaining IRB approval, we submitted our study protocol, consent forms, and other supporting documents to the Human Research Protection Office (HRPO) on 11/19 for its review and approval. We then requested an update on the status on 12/19 and received a response in the same month indicating that it had just been assigned for initial review, which should be completed within 15 business days. We again requested an update on 1/17/2020 and received a response on 1/21/2020 indicating that the initial review had been completed and that the review process had progressed to the next step. We submitted requested clarifications and edits to the Human Research Protection Office (HRPO) on 3/17/20 and final approval was received on 3/20/20.

3.2.3. Review and test the online database

All provider and English versions of the parent surveys have been programmed into REDCap. Staff members completed the process of reviewing and testing all of the surveys for functionality to ensure question content and branching logic have been accurately programmed and there are no technical “bugs”. We have also programmed all of the Spanish versions of the parent surveys as well.

3.2.4. Hiring and training the research team

We originally hired Kisna Prado as Research Coordinator and recently replaced her with John Hershberger after she accepted another position in May 2020. On 6/1/20, Taylor Kalmus began in a Research Study Assistant position. She has been trained on all assessments and study activities to the extent while remaining blind to study design. Catherine Dick, who is a 4th year graduate student in the UW Clinical Psychology doctoral program, provided her expertise on behavioral assessments and coding systems, reviewing the research protocol, and training of other staff. Shana Attar and Hannah Neiderman, who are 1st year graduate students in the Clinical Psychology program (also mentored by PI Stone), made progress on learning the behavioral assessments (Attar) and becoming reliable on the coding schemes (Neiderman).

3.2.5. Translating materials into Spanish

We contracted with an experienced translator who has content expertise to translate surveys, questionnaires, consent forms, and recruitment materials. Thus far all consent, recruitment, and screening materials have been translated and only 3 surveys remain. The translations that have been completed have been reviewed by the first Research Coordinator Prado and Co-Investigator Ibañez for accuracy and cultural appropriateness.

3.2.6. Clinicaltrials.gov registration

We created and filled out our study profile on Clinicaltrials.gov and will formally submit it as soon as the necessary Covid-related adaptations can be made to the study protocol to accommodate family recruitment and assessment.

3.2.7. Training on user experience research methods

Co-I Ibañez pursued training on user experience methods through online workshops and by reading supplementary materials on user experience research techniques. These methods include survey development, interviewing, focus groups, and qualitative data synthesis techniques such as user journey mapping and affinity diagramming.

3.2.8. Engaging with interested EI programs and EI providers

In initiating engagement efforts, PI Stone, Co-I Ibañez, and former Coordinator Prado met with 2 EI programs to conduct information sessions in late 11/2019. During these sessions, the research team met with EI providers directly to describe and discuss the nature of the study. After all information sessions, provider teams were given the opportunity to discuss study activities internally and request clarification from the research team. Shortly after receiving final HRPO approval on 3/20/20, Washington State put in place a shelter-at-home order on 3/26/20, and our IRB has also mandated

that no in-person visits be conducted. Therefore, COVID-19 delayed the recruitment and enrollment of EI providers, as well as the subsequent recruitment and enrollment of families (who are recruited from provider caseloads).

To adjust to the current circumstances and move forward with the enrollment process, we developed different strategies for engaging with EI programs. We contacted the EI program leads to let them know the study received approval from HRPO and also to pass along important and helpful resources for working with families during the pandemic, which we complied from many different organizations and experts. We again reached out to them to set up a time in 5/2020 to remind them about the study details and discuss their programs' priorities and identify the best way to re-engage with providers (e.g., present the study to them via Zoom). To promote and incentivize their participation in the study, we brainstormed with the EI directors for potential resources that providers would find useful and that we are uniquely positioned to provide. For example, we shared a web-based tutorial that was developed to help parents engage children with autism in their everyday home routines (snacktime, bedtime, bathtime, and family playtime) and has been shown to be efficacious (Ibanez et al., 2018). We also shared information about an in-home, play-based assessment that may be used with families during "virtual" sessions, which might be a helpful tool for collecting systematic observations of children's social communication. Our clinical psychologist on the research team, Dr. Karen Bearss, also has extensive experience in telehealth consultations with families with children with ASD and has provided additional guidance and helpful tips for remote observation of child behaviors and parent coaching.

At the end of July 2020, we re-engaged with providers by holding 3 1-hour webinars with two agencies and multiple regional teams to provides study details and outline the next steps for enrollment and data collection. We anticipated that we will hold more of these webinars for other interested providers.

3.2.9. Enrolling EI providers and beginning T1 data collection

After the webinars at the end of July 2020, we sent the link to the online consent form so that interested providers could formally provide informed consent and enroll, and then be automatically directed to their first survey on REDCap. As of 8/11/20, there have be 5 providers that have enrolled and 4 of them have completed their T1 survey. In addition to primary survey items that ask about their intervention practices, we also expanded items to identify the ways in which their work with families has changed since the pandemic, which will allow us to better understand the needs of EI providers during the study.

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

Dr. Stone taught three, weekly research seminars during the Fall 2019, Winter 2020, Spring 2020 quarters that included both post baccalaureate and graduate students, and involved discussion of research activities, methodological approaches, and the latest findings in topic areas related to the current study. All 4 of her graduate students (i.e., Dick, DesChamps, Attar, & Neiderman) participated in this seminar.

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) complete enrollment of EI providers; (2) continue data collection for EI providers; and (3) randomize EI providers to one of two recruitment arms (i.e., Video only group or Video+Clinic Group). While we also plan to begin recruitment, enrollment, and data collection with families next quarter, those activities are entirely contingent on the shelter-at-home and social distancing policies dictated by our local and state officials, as well as UW and IRB regulations.

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. However, as mentioned above, we are developing strategies for moving forward with enrollment and data collection through the use of web-based technology.

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. 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:	*No change (1.04 RDM)*
Contribution to Project:	*Dr. Stone has been overseeing all study activities and directing the course of study.*
Funding Support:	

Name:	*Lisa Ibañez*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	0000-0002-7084-3375
Nearest person month worked:	*2.1 (5.21RDM)*
Contribution to Project:	*Dr. Ibañez has been overseeing all study activities and providing support for the direction of the study.*

Funding Support:	

Name:	*Jill Locke*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	0000-0003-1445-8509
Nearest person month worked:	*No change (0.45 RDM)*
Contribution to Project:	*Dr. Locke has been providing consultation on the implementation aspects of the study.*
Funding Support:	

Name:	*Karen Bearss*
Project Role:	*Clinician*
Researcher Identifier (e.g. ORCID ID):	0000-0002-1559-146X
Nearest person month worked:	*No change (.8 RDM)*
Contribution to Project:	*Dr. Bearss has been providing feedback on issues related to the behavioral assessments.*
Funding Support:	

Name:	*Catherine Dick*
Project Role:	*Graduate Student*

Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*No change (0 RDM)*
Contribution to Project:	*Ms. Dick has been providing support related to the review of behavioral assessments and coding.*
Funding Support:	NIH 5R01DC013767-05

Name:	*Hannah Neiderman*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*No change (.45 RDM)*
Contribution to Project:	*Ms. Neiderman has been preparing to perform behavioral assessments.*
Funding Support:	NIH 5R01DC013767-05

Name:	*Shana Attar*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*No change (0 RDM)*
Contribution to Project:	*Ms. Attar has been preparing to perform behavioral assessments.*
Funding Support:	NIH 5R01DC013767-05

Name:	*Kisna Prado*
Project Role:	*Research Study Coordinator*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*2.4 (4.28 RDM)*
Contribution to Project:	*Ms. Prado has been coordinating initial study activities under the guidance of PI Stone and Co-I Ibañez.*
Funding Support:	

Name:	*Sabine Scott*
Project Role:	*Research Study Assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3 (8.24 RDM)*
Contribution to Project:	*Ms. Scott has been preparing to perform behavioral assessments and reviewing the RIT training materials.*
Funding Support:	

Name:	*Pascale Carpentier*
Project Role:	*Research Study Assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*1.5 (4.26 RDM)*

Contribution to Project:	*Ms. Carpentier has helped with the review of all Spanish translations and review of Spanish surveys in database. She also assisted with the transition between research coordinators in May.*
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.