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TITLE: Clinicianless Training in Autism Treatment: An Adaptive Online Parent Education Program

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14. ABSTRACT

This research project focuses on the development and evaluation of a self-directed smartphone application designed to facilitate mass dissemination of a parent training program in Pivotal Response Treatment, a well-established and highly effective intervention for young children with autism. Human subjects approval, research team hiring and training, creation of the REDCap project management program, and development of the app were all completed during this annual report period. During the remaining grant funding period, we will test two versions of this app in a randomized clinical trial with 48 families living in the United States. One version will be a standard training app with eight learning modules, video examples, practice opportunities, and the ability to record and upload parent-child practice videos. The other version will also contain the ability to review and self-score one's performance in order to get feedback on one's mastery of the intervention techniques. Examined project outcomes include parent mastery (fidelity of implementation) of the intervention strategies (primary outcome), coded parent and child social behavior from video samples, and child developmental survey scores (secondary outcomes).

15. SUBJECT TERMS

Autism, early intervention, parent education, smartphone app, app-based training, clinical translational research, dissemination

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1. INTRODUCTION:

Families across the United States experience many geographical, financial, and logistical barriers to accessing effective early autism intervention for their children. Such intervention efforts are crucial for optimizing child developmental outcomes and preventing long-term cognitive, social, and behavioral difficulties. In response to this public health challenge, the purpose of this research project is to develop and evaluate a self-directed smartphone application designed to train parents in Pivotal Response Treatment, a well-established and highly effective intervention for young children with autism. During the first phase of this project, project researchers partnered with software engineers to develop an interactive training app with eight learning modules, video examples, interactive practice opportunities, and the ability to record and upload parent-child practice videos for data collection purposes. During the next phase of this project, this app will be tested in a randomized clinical trial with 48 families living in the United States. Families who meet inclusion criteria will be randomized to one of two versions of the app: one version will be a standard training app, while the other version will also contain the ability to review and self-score one's performance in order to obtain ongoing feedback on one's mastery of the intervention techniques. The primary outcome from this research study is caregiver mastery of the learned intervention strategies (fidelity of implementation). Secondary outcomes include coded parent and child social behavior from family-submitted video samples and a range of child developmental survey scores. It is hypothesized that families in the video-self scoring condition will experience superior outcomes on both primary and secondary outcomes. Ultimately, this project is intended to serve as an important step in a line of research that will enable mass dissemination of evidence-based autism interventions without the need for ongoing professional training by expert clinicians.

2. KEYWORDS:

Autism, early intervention, parent education, smartphone app, app-based training, clinical translational research, dissemination

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of the project are to (1) develop two versions of a smart-phone apps designed to train parents in autism early intervention strategies, (2) conduct a pilot

randomized clinical trial to assess feasibility, utility, and preliminary efficacy of the two app-based programs, and (3) determine if the app featuring parent self-scoring of performance yields superior gains in parent treatment implementation and child developmental outcomes when compared to a basic version of the app without this functionality.

There were five major tasks delineated in the project Statement of Work (SOW). Each major task and progress on associated milestones are summarized below:

Major Task 1: Major Task 1 is to obtain IRB/Human Subjects approval and complete secondary review by the DoD Human Research Protection Office (HRPO) for the project's planned clinical trial. The associated milestone was Institutional IRB approval and DoD HRPO secondary review approval. The target date for this milestone was December 31, 2020 and the actual completion date was August 31, 2020. This milestone was met. **This major task is complete.**

Major Task 2: Major Task 2 is to complete all project research staff hiring and training procedures in preparation for the clinical trial. The first associated milestone was to complete all research staff hires. The target date for this milestone was September 30, 2020 and the actual completion date was October 23, 2020. This milestone is complete. The second associated milestone was to complete all staff training in the project standard operating procedures/clinical trial protocol, which included procedures for participant recruitment and retention, consent and assessment processes, and data collection, management, and analysis. The target date for this milestone was February 28, 2021 and the actual completion date was May 31, 2021. This milestone was met. **This major task is complete.**

Major Task 3: Major Task 3 is to work with Novacoast Inc. to develop and revise the parent training smart phone applications focused on the Pivotal Response Treatment early autism intervention model for the project clinical trial. The first associated milestone is to complete the initial version of the Pivotal Response Treatment app for participant use in the clinical trial. The target date for this milestone was March 31, 2021 and the actual completion date was June 30, 2021. The second associated milestone is to revise the Pivotal Response Treatment apps after the clinical trial in preparation for a future large scale clinical trial. Progress on this milestone is not scheduled to begin until the onset of the clinical trial (when users are able to provide beta software feedback on the apps). **Progress on this second milestone is on track and currently at 85% completion.**

Major Task 4: Major Task 4 is to conduct a pilot randomized clinical trial (RCT) with the Pivotal Response Treatment smartphone applications with a total of 48 participants. The first associated milestone is to recruit an initial cohort of 24 participant dyads (parent-child pairs) for the clinical trial. The original target date for this milestone was May 31, 2021 and the actual completion date was December 27, 2021. This milestone was completed. The second associated milestone was completion of the last cohort of 24 participant dyads. The start date for recruitment of the second cohort was originally

scheduled to begin 10/1/2021 and actually began 1/1/2022. 20 of the final 24 participants have been completed by 6/30/2022. **Progress on this milestone is currently at 83.33%**

Major Task 5: Major Task 5 is to complete data collection and analysis of the project clinical trial data. The first associated milestone is to complete the creation and configuration of the REDCap project database. REDCap is a secure online program for research project and database management. The target date for this milestone was December 31, 2020 and the actual completion date was December 23, 2020. This milestone is complete. The second associated milestone of Major Task 5 is to analyze all clinical trial data. The milestone activities began on October 1, 2021 with a revised target completion date of December 2022. **Progress on this second milestone is currently at 57%.**

What was accomplished under these goals?

Major Activities:

Commencement of Clinical Trial: With the Pivotal App completed and ready for deployment at the end of Year 1, the clinical trial phase of the project began at the start of Year 2. A total of 44 of the 48 participant family dyads have been recruited for the project.

Simons Foundation SPARK Partnership: This DoD research project was selected as a SPARK partner project and thus, SPARK staff will assist the research team with recruiting participants that fit project inclusion criteria from their database of thousands of individuals with autism.

Presentation of Preliminary Outcomes: A research symposium featuring the preliminary outcomes of this project's clinical trial was accepted by and presented at the International Society of Autism Researchers (INSAR) Annual Meeting in Austin, Texas, featuring significant improvements in intervention fidelity (see significant results below).

Specific Objectives:

The specific objective of this project is to facilitate dissemination and accessibility of an evidence-based autism intervention, Pivotal Response Treatment, to parents of young children with autism. The proposed project will focus on the development and comparison of two smart-phone/tablet apps designed to deliver instructional content to families nationwide: (a) an adaptive version in which parents engage in video self-modeling/self-score their own Pivotal Response Treatment fidelity of implementation

(FOI) and receive customized feedback and (b) a standard lesson-based Pivotal Response Treatment app without this functionality.

In Year Two, all research efforts have focused on the successful recruitment and enrollment of clinical trial families, along with analysis of their fidelity and child developmental improvements.

Significant Results or Key Outcomes:

In the symposium presentation at the INSAR Annual Conference, PI Ty Vernon presented on the outcomes of the first eight families to complete the Pivotal app in this project's clinical trial. These parent participants significantly improved their use of intervention components from a mean of 66.1% to 78.4% ($F(4,28) = 3.360$ $p = .023$; Cohen's $d = 0.74$, which was indicative of a large effect size. When analyzing the mean percent of intervention trials with all intervention components used, parents improved from a baseline mean of 23.2% to an intervention mean of 44.4% ($F(4,28) = 2.851$ $p = .042$; Cohen's $d = 0.72$, which was indicative of a large effect size.

Other Achievements:

Nothing to Report

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

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

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

A no-cost extension was approved to complete enrollment of the final clinical trial participants and complete trial data analysis. Specifically, efforts will focus on completing

analysis of parent intervention fidelity improvements (primary outcome) and analyzing child social communication and developmental improvements (secondary outcomes).

4. IMPACT:

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

The research team has received very positive feedback from family participants who have used the Pivotal app to learn early autism intervention strategies that they can use with their children. We hope that the app will facilitate wide-spread dissemination of a efficacious treatment model for children on the autism spectrum, while inspiring other researchers to package their interventions in a similar manner. Presentation of our preliminary findings at the INSAR autism research conference has led to several promising collaborations for future app-based projects focused on social skill competencies, management of behavioral challenges, adaptive skill building, and bilingual early intervention programs.

What was the impact on other disciplines?

We believe that this project's smartphone app is still likely to have an impact in the disciplines of education and medicine. If the app is successful in facilitating skill mastery using video examples and video-self modeling, similar methods can be used to supplement or augment learning in a special education classroom setting and/or increasing a child's comfort in a doctor's office or treatment adherence in a medical setting.

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

We continue to believe that society as a whole needs easy access to cutting edge interventions, and that parents can be empowered with simple strategies to alter the course of their child's development. The results from this project are likely to change public perception of how autism intervention methods can be effectively disseminated directly to families in need. By leveraging the ubiquitousness of smartphones and existing research on the effectiveness of online parent training and video self-modeling, this project outcomes challenge the belief that caregivers require live training from professional clinicians in order to master early intervention methods, thus removing historic geographical, logistical, and financial barriers to accessing gold standard autism treatment models.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Beyond project delays due to the PI's health condition (see below), there have been no significant changes in the project or its direction. We have partnered with the Simons Foundation SPARK program as an additional recruitment source.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Starting in Year 1 and spanning into Year 2, PI Dr. Vernon was diagnosed with colorectal cancer in December 2020 and completed intensive radiation, chemotherapy, and multiple surgeries (18 weeks) from January 2021 to February 2022. These procedures and associated recovery periods pushed back the onset of the clinical trial phase until the start of Year 2. Recruitment strategies (including our partnership with the SPARK program) have been very successful and we have 83.3% of our total trial participants recruited.

There have been some challenges getting a subset of participant families to continue progressing through the app-based intervention training program, particularly during the later modules. This was an anticipated challenge of a self-directed training program without regular face-to-face contact. Some participants who have remained unresponsive have been terminated from the project. To address this issue, we have employed the planned use of in-app notifications, emails, and phone calls as part of a multipronged strategy to remind participants to return to the app on a regular basis to complete the next lesson.

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

Ferguson, E., Arias,, A., Jimenez-Munoz, M., Licona, S., Russell, K.; Adams, P., Nees, A., & Vernon, T., (2022, May). *Pivotal for Early Autism Intervention: Preliminary Fidelity Improvements Associated with a Smartphone App-Based Parent Education Program*. Oral presentation in Leveraging Diverse Digital Technologies to Disseminate

Evidence-Based Autism Interventions at the International Meeting for Autism Research, Austin, TX, USA.

Books or other non-periodical, one-time publications

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

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

The smartphone app *Pivotal* was developed, revised, and approved by the UCSB research team and Novacoast Inc. software engineers for use by the clinical trial participants of the current project.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Ty Vernon
Project Role:	Principal Investigator
Researcher Identifier:	ORCID ID# 0000-0001-6042-2182
Nearest person month worked:	4 person months
Contribution to Project:	Dr. Vernon oversaw implementation of the proposed project; coordinated and conducted weekly research staff meetings; supervised research staff working on the project, monitored progress on grant milestones, and assisted with creation of systems and procedures to facilitate data collection, organization, and analysis efforts via REDCap.
Name:	Andrew Maul
Project Role:	Co-Principal Investigator/Statistician
Researcher Identifier:	ORCID ID# 0000-0003-0728-1880
Nearest person month worked:	3 person months
Contribution to Project:	Dr. Maul continues to assist with participant data analysis, including safeguards for quality assurance/data management and protection.
Name:	Emily Ferguson
Project Role:	Graduate Student Researcher/Project Manager
Researcher Identifier:	N/A
Nearest person month worked:	3 person months
Contribution to Project:	Ms. Ferguson was responsible for overseeing day-to-day operations of the project, co-development of the standard operating procedures with PI Vernon, overseeing participant recruitment and progress monitoring, and ensuring that all videos and data were uploaded for analysis.
Name:	Sarely Licona
Project Role:	Graduate Student Researcher/Assistant Project Manager
Researcher Identifier:	N/A
Nearest person month worked:	3 person months
Contribution to Project:	Ms. Licona was responsible for training and supervising our team of intervention fidelity coder

research assistants for the scoring of our primary outcome measure.

Remaining project staff (graduate and undergraduate students) have all worked less than one person month during this reporting period.

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?

Organization Name: Novacoast, Inc.
Location of Organization: Santa Barbara, California
Partner's contribution to the project: Collaboration

Novacoast, Inc. has served as a key partner organization on this research project. Their software engineers have worked with the research team at UCSB to convert existing Pivotal Response Treatment intervention presentation content, training materials, and video examples into the completed smartphone application. Biweekly team meetings and ongoing email communication were used to develop the eight intervention modules, test preliminary versions of the app, and release new app versions in response to research team feedback.

8. SPECIAL REPORTING REQUIREMENTS

Nothing to Report

9. APPENDICES:

Award Chart

AR190105: Clinicianless Training in Autism Treatment: An Adaptive Online Parent Education Program

PI: Ty Vernon, UC Santa Barbara, California **Budget:** $738,769

Topic Area: Autism Research Program **Mechanism:** Clinical Translational Research Award

Research Area(s): 0820, 1605

Award Status: Year 2 Completed, NCE Approved
Total Project Period 7/1/20 - 6/30/23

Study Goals:

The goal of this study is to facilitate widespread dissemination and accessibility of a well-established, evidence-based early autism intervention, Pivotal Response Treatment (PRT), to caregivers of young children with autism nationwide. The current project focuses on the development and comparison of two versions of a smartphone app-based intervention training program in the context of randomized clinical trial. These apps are designed to train caregivers in the PRT intervention model without the need for direct clinician involvement. The adaptive version of the app will have parents review and self-score their own performance of the intervention strategies (fidelity of implementation) in order to receive customized feedback. This version will be compared to a standard lesson-based PRT app without this video self-scoring functionality.

Specific Aims: The specific aims of this investigation are to (1) develop PRT smartphone applications that combine instructional videos and lessons with video capture and video self-modeling/fidelity analysis functionality (2) conduct a pilot randomized clinical trial to assess the feasibility, utility, and preliminary outcome efficacy of these two versions of the PRT training app as promising mechanisms to disseminate evidence-based autism intervention to the general public, and (3) determine if a PRT app with video self-modeling/fidelity self-scoring yields superior gains in parent fidelity and child outcomes over the basic version of this app.

Key Accomplishments and Outcomes:

Publications: none to date

Patents: none to date

Funding Obtained: none to date