

**AWARD NUMBER:** W81XWH-20-1-0248

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

**PRINCIPAL INVESTIGATOR:** Vernon, Ty, W.

**CONTRACTING ORGANIZATION:** University of California, Santa Barbara, CA

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b> N/A						
<b>14. ABSTRACT</b> 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).						
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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 that 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). Milestone activities are scheduled to begin July 1, 2021; therefore, progress on this second milestone is currently at 0%.

**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 (Month 11) but this target date has been delayed. Milestone activities are now scheduled to begin 7/1/2021 with a revised target completion date of 8/31/2021, therefore, progress on this first milestone is currently at 0%. The second

associated milestone was completion of the last cohort of 24 participant dyads. The start date for recruitment of the second cohort is 10/1/2021 and the target date for completion of this milestone remains at 11/31/2021 (Month 17), therefore, progress on this second milestone is also currently at 0%.

**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 are scheduled to begin October 1, 2021 with a target completion date of May 31, 2022 (Month 23); therefore, progress on this second milestone is currently at 0%.

## What was accomplished under these goals?

### Major Activities:

Research Team Training: In this annual reporting period, research staff training on the clinical trial protocol, data collection, quality assurance safeguards, and project management using REDCap as a project management program was completed. Standard operating procedures have been fully developed, tested, and deployed for the clinical trial. Research assistant training in Noldus Observer XT for behavioral coding of Pivotal Response Treatment parent fidelity and parent/child social behaviors has also been completed.

REDCap Project Database: REDCap database and participant workflow protocol (including recruitment processes, screening questionnaires, consent procedures, intake assessment administration, randomization and group assignment procedures, program progress monitoring, video data entry, and final assessment administration) has been completed. All participant questionnaires and surveys have been added or created, internally tested, and finalized for clinical trial implementation.

Pivotal Response Treatment Parent Education Smartphone App Development: Smartphone application development for the clinical trial was completed during this reporting period. This process included creation, testing, and revision of the eight intervention modules based on existing instructional content and video examples, creation of the video recording and upload functionality, and development of the parent video self-scoring modules. Each intervention module includes review of key concepts, video examples, interactive practice exercises, and comprehension quizzes.

**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.

The research efforts of the first year have put in place all required components to implement the upcoming clinical trial in Year 2, including human subjects and HRPO approval, research team training in project standard operating procedures and data collection/analysis methods, and creation and testing of the Pivotal Response Treatment intervention smartphone apps.

**Significant Results or Key Outcomes:**

The clinical trial phase, scheduled to begin next quarter (first quarter of year two), will generate the outcome data to inform the significant results/key outcomes of this project. It is anticipated that these outcomes will support the feasibility and acceptability of a smartphone app-based parent training program and provide promising evidence of efficacy for current and future participants.

**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?**

The clinical trial planned for Year 2 of the project period will enable our research team to recruit and analyze the outcomes of 48 families who have a young child with autism. Our team will specifically analyze caregiver mastery of the Pivotal Response Treatment intervention strategies (fidelity of implementation) over time as the primary outcome measure to evaluate the preliminary efficacy of this app-based training method.

**4. IMPACT:**

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

The completed Pivotal Response Treatment app is likely to influence how other clinical psychology and autism intervention researchers leverage available technology to facilitate wide-spread dissemination of efficacious treatment models for children and adults on the autism spectrum. Dissemination constitutes a bottleneck in the efforts to get effective intervention methods in the hands of individuals and families that need these strategies the most. This research is likely to encourage other research groups to develop similar apps to train parents and individuals on the autism spectrum in a variety of skill domains, including language development, social skill competencies, management of behavioral challenges, adaptive skill building, and job/vocational training.

**What was the impact on other disciplines?**

The project's smartphone app is also 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 encourage 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?**

The results from this project are likely to impact 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 aims to 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.

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

As previously reported, PI Dr. Vernon was diagnosed with colorectal cancer in December 2020 and completed intensive radiation (5.5 weeks) and chemotherapy treatments (18 weeks) from January to July 2021. During this project period, Dr. Vernon continued to lead weekly grant team meetings and fulfill his grant-related duties. However, Dr. Vernon's medical treatments and overall physical health resulted in moderate delays in the original grant timeline. The onset of clinical trial recruitment is now anticipated to begin in the first quarter of Year 2 instead of the last quarter of Year 1 (a one quarter delay). By reducing the time between the recruitment of the two participant cohorts, the impact on the overall project timeline will be minimized. Specifically, instead of waiting for the entire first cohort of 24 participants to complete the project prior to recruiting the second cohort of 24, the UCSB research team will recruit and enroll participants in the second cohort while members in the first cohort are still completing the final stages of the project. The research team will request the one-year no cost extension option as needed to complete all grant major tasks and meet the associated milestones.

**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**

Nothing to Report

**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 helped to create and manage the project data workflow (REDCap database and procedures) to ensure timely and accurate data collection, organization, and 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, assisting with the design and modification of Pivotal Response Treatment app lessons, and training and supervising undergraduate research assistants to code participant videos.

Name: Maria Jimenez Munoz  
 Project Role: Graduate Student Researcher/Assistant Project Manager  
 Researcher Identifier: N/A  
 Nearest person month worked: 3 person months  
 Contribution to Project: Ms. Munoz was responsible for co-developing and configuring the REDCap project platform with Co-PI Maul, assisting Ms. Ferguson with overseeing day-to-day operations of the project, assisting with the design and modification of Pivotal Response

Treatment app lessons, and training and supervising undergraduate research assistants in REDCap data entry procedures.

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

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**Research Area(s):** 0820, 1605

**Award Status:** Year 1 Completed

Total Project Period 7/1/20 - 6/30/22

## **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