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

PRINCIPAL INVESTIGATOR: Dr. Ty Vernon

CONTRACTING ORGANIZATION: University of California, Santa Barbara

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14. ABSTRACT This research project focused 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. We evaluated two versions of this app in a randomized clinical trial with 48 families living in the United States. One version of the app was a traditional training app with eight learning modules, video examples, practice opportunities, and the ability to record and upload parent-child practice videos. The other version of the app also contained the ability to review and self-score one's performance in order to get feedback on one's mastery of the intervention techniques. Outcomes from the project revealed that use of the self-scoring app version was associated with superior parent mastery of the intervention strategies (fidelity of implementation) when compared to those the non-self-scoring app condition. Participant use of either app was associated with comparable improvements in child expressive language use and responsiveness, with families in both conditions completing a similar number of in-app learning modules.						
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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Families across the United States experience a number of barriers—geographical, financial, and logistical—when attempting to access 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 challenges. In response to this public health challenge, the purpose of this research project was 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 the project, the app was tested in a randomized clinical trial with 48 families living in the United States. Families who met inclusion criteria were randomized to one of two versions of the app: (1) a standard e-learning training app, or (2) a fidelity self-scoring app version that included the functionality to review and self-score one’s video-recorded performance in order to obtain ongoing feedback on one’s mastery of the intervention techniques. The primary outcome from this research study was caregiver mastery of the learned intervention strategies (fidelity of implementation). Ultimately, this project was 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 in-person sessions or ongoing professional consultation by expert clinicians.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

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 were 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 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 was completed.**

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 was completed.**

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. This milestone was completed in May 2023. **This major task was completed.**

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. The final 24 participants were all enrolled by 6/30/2022. **This major task was completed.**

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 were completed in December 2023. **This major task was completed.**

What was accomplished under these goals?

Major Activities:

Completion of the Clinical Trial: The Pivotal App was designed, created, and launched at the end of Year 1. The clinical trial phase of the project began at the start of Year 2, and a total of 48 participant family dyads were recruited for the project. The clinical trial concluded in Year 3.

Presentation of 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 Meetings in Austin, Texas (2022) and Stockholm, Sweden (2023), featuring significant improvements in intervention fidelity.

Specific Objectives:

The specific objective of this project was to facilitate dissemination and accessibility of an evidence-based autism intervention, Pivotal Response Treatment, to parents of young children with autism. The project focused 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. During this clinical trial, all research efforts 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:

Primary Outcome: Research assistants, masked to the treatment condition and video sequence, scored videos for multiple measures of PRT treatment fidelity, including (1) mean percentage of PRT component use and (2) percent of trials with *all* PRT components (a more stringent measure of fidelity)

A series of mixed Group x Time ANOVAs revealed superior outcomes associated with parents randomly assigned to the fidelity self-scoring app condition (vs the non-scoring app condition).

For Mean PRT fidelity, there was a significant interaction between the app condition and time on mean fidelity percentage, $F(1, 46) = 12.86, p < .0005$, partial $\eta^2 = .218$. Participants in the self-scoring condition demonstrated evidence of increased mastery post-trial (mean 79.25%; SD 15.24%) when compared to the non-scoring condition (mean 72.75%; SD 15.23%).

For Trials with All PRT components, there was also a significant interaction between the app condition and time, $F(1, 46) = 6.06, p = .018$, partial $\eta^2 = .116$. Participants in the self-scoring condition demonstrated increased use of all components post-trial (mean 51.33%; SD 32.47%) versus the non-scoring condition (mean 41.67%; SD 27.86%).

Secondary Outcomes:

Child Expressive Language Use: There was no evidence of one app version having a superior effect on child language, as there was not a significant interaction between app condition and time on child expressive language use. However, the main effect of time showed a statistically significant increase in mean language use across participants in both app conditions, suggesting that both Pivotal app versions were successful in increasing child vocalizations, $F(1, 46) = 6.29, p = .024$, partial $\eta^2 = .295$. Across the combined cohort, child vocalizations increased from a mean of 10.12 (SD 8.33) per 10-minute video at intake to 16.44 (SD 14.56) at post-trial participation.

Child Responsiveness: There was not a significant interaction between app condition and time on child responsiveness to parent bids. However, the main effect of time also showed a statistically significant increase in mean responsiveness across participants in both app conditions, suggesting that both app versions were successful in increasing responsiveness to parent-initiated language bids, $F(1, 46) = 9.07, p = .009$, partial $\eta^2 = .377$. Across the combined cohort, child responsiveness increased from a mean of 10.12 (SD 8.33) per 10-minute video at intake to 16.44 (SD 14.56) at post-trial participation.

Parent Initiations: For number of parent-initiated language bids, there was *not* a significant group x time interaction, with a comparable number of ABC trials post-trial across self-scoring (mean 3.92; SD 3.96) and non-scoring (mean 6.5; SD 7.85) conditions.

Parent Module Completion: There was a concern that the additional time and effort required to review and self-score fidelity of implementation would be aversive to families in the self-scoring condition and cause families to prematurely discontinue using the app. However, analysis of app module completion using an independent sample T-test revealed no significant difference in number of completed app modules between conditions, $t(46) = 1.158, p = .255$. Those in the self-scoring condition actually completed a greater mean number of app modules (mean 5.06 [SD 3.03] versus 3.89 [2.85]), however, this difference was not statistically significant.

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?

N/A

- 4. IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

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

This work directly benefited the field of autism research and applied psychology by developing a proof-of-concept app to promote mass dissemination of accessible autism intervention training. This grant was a crucial step in a systemic line of research towards creating accessible solution for families that transcends several historic barriers limiting service utilization, such as limited transportation, scheduling, and availability of qualified clinicians. 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 an efficacious treatment model for children on the autism spectrum, while inspiring other researchers to package their interventions in a similar manner. Presentation of our 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?

This project's smartphone app is anticipated to make an impact in disciplines of education and medicine. As this app and similar virtual training efforts have been successful in facilitating parent and professional skill mastery using video examples and video-self modeling, similar methods have been explored 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. This research adds to the growing trend of using digital dissemination methods across disciplines.

What was the impact on technology transfer?

The final versions of the Pivotal App are ready for use in a larger scale clinical trial. Steps to commercialize the apps will be completed following the empirical validation of the follow-up clinical trial.

What was the impact on society beyond science and technology?

This research grant was an important step in providing the general public with easy access to cutting edge autism interventions. Parents were empowered with simple evidence-based 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.

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.

During May 2023, PI Dr. Vernon experienced a recurrence of cancer and was placed on medical leave for surgery and chemotherapy, which will be completed in January 2024. The timing of this diagnosis and leave delayed the completion of this final report and the publication of related research manuscripts. It is anticipated that a series of manuscripts will be submitted following Dr. Vernon's return from medical leave in the next few months.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

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:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

Publications, conference papers, and presentations

Branyan, S., Licona, S., Ferguson, E.F., Arias, A., Jimenez-Munoz, M., Russell, K.M., and Vernon, T.W. (2023, May). *Improvements in Parent Use of Contingency through App-Based Training in the Pivotal Response Treatment Intervention Model*. International Society of Autism Researchers Annual Meeting, Stockholm, Sweden.

Bordofsky, A., Licona, S., Ferguson, E.F., Jimenez-Munoz, M., Arias, A., Russell, K.M., and Vernon, T.W. (2023 May) *Increasing Child Responsiveness to Social Communication Bids: Results from the Pivotal App Clinical Trial*. International Society of Autism Researchers Annual Meeting, Stockholm, Sweden.

Vernon, T., Licona, S., Ferguson, E. Jimenez-Munoz, M., Arias, A. Russell, K., Anderson, D., Kim, M. (2023, May) *Increases in child language attempts following parent training in Pivotal Response Treatment: Results of the Pivotal app-based parent education program*. International Society of Autism Researchers Annual Meeting, Stockholm, Sweden.

S. Licona, S., Elizalde, I., Kim, A. Teodoro, S., Walton, B., Jimenez Munoz, M., Russell, K. M., Ferguson, E., Arias, A., Vernon, T.W. (2023, May) *Improvements to Parent Intervention Fidelity and Dosage after Participation in a Pivotal Response Treatment App-Based Training Program*. International Society of Autism Researchers Annual Meeting, Stockholm, Sweden.

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
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
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
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: Maria Jimenez Munoz
Project Role: Graduate Student Researcher/Assistant Project Manager
Researcher Identifier: N/A
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 data entry procedures.

Name: Sarely Licon
Project Role: Graduate Student Researcher/Assistant Project Manager
Researcher Identifier: N/A
Contribution to Project: Ms. Licon was responsible for training and supervising our team of intervention fidelity coder research assistants for the scoring of our primary outcome measure.

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
Transition Plan

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: Project Completed
Total Project Period 7/1/20 - 6/30/23

Study Goals:

The goal of this study was 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 project focused 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 were designed to train caregivers in the PRT intervention model without the need for direct clinician involvement. The adaptive version of the app had parents review and self-score their own performance of the intervention strategies (fidelity of implementation) in order to receive customized feedback. This version was compared to a standard lesson-based PRT app without this video self-scoring functionality.

Specific Aims: The specific aims of this investigation were 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 would yield 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

Transition Plan Questionnaire

Directions: Please answer all questions that apply for each product under development. Please fill out one document per product. *This is not an application for funding; however, answers will help us understand the outcomes and products from your award.*

1. After the award closes, would you be willing to periodically provide voluntary information (via email) regarding the project status (i.e. where the research is headed)? **Yes** or **No**

These responses will help CDMRP demonstrate the return on its investments and will help demonstrate that the CDMRP is a responsible and successful steward of federal research funding.

2. What **conclusion(s)** does your final data support?

3. Will you/have you applied for/obtained follow-on-funding for this project? **If yes**, please list (a) funding organization, (b) total budget requested/obtained, and (c) title of the funded proposal. *This information will be recorded as an outcome to this award.*

4. What will be **the next step(s)** for this project?

5. How would you classify your **lead candidate product**? *Please choose the best option or add explanation for multiple selections.*

(a) Therapeutic (Small Molecule, Biologic, Cell/Gene Therapy):

(b) Diagnostic

(c) Device

(d) Research Tool to Address a Research Bottleneck

(e) Knowledge Product (Non-material product such as a compound library, database, something that improves clinical practice, education, etc.)

(f) Other - Please Specify:

6. How does your candidate product aid the Warfighter, Veteran, Beneficiary, and/or General Population?

7. Therapy / Product Development, Transition Strategies, and Intellectual Property

Describe the steps and relevant strategies required to move the candidate product (knowledge or tangible) to the next phase of development and/or commercialization. Please address any issues with intellectual property.

PIs are encouraged to explore the technical requirements and the current regulatory strategies involved in product development as well as to work with their organization's Technology Transfer Office (or equivalent regulatory/legal office), federal/international regulatory experts, to develop the transition plan and to explore developing relationships with industry, DoD advanced developers (e.g. USAMMDA), and/or other funding agencies to facilitate moving the product into the next phase.