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

ID: 24-21-0034

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APPLICATION FOR HUMAN SUBJECTS USE

Protocol Number: 24-21-0034

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Project Type: Faculty-led

Proxy(s):

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Collaborations:

Name	Institution	IRB Approval Through Home Institution

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

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

DoD: *Does your project have DoD funding?* -Yes

Funding Source:

ORBiT Funding Source: US Army Medial Research Acquisition Activity - 20200072

Clinical Trial: Yes

Admin Dept/ORU: CCSP

Submission Type: R-Renewal No Changes

PROTOCOL SUBMISSION - ELECTRONIC SIGNATURE PAGE

By clicking the "I agree" button on the electronic signature page in ORahs, I certify in my capacity as the role of the investigator or faculty advisor that this study will be conducted in the manner described in the protocol and that the research team will adhere to the ethical and scientific standard for conducting human subjects research. All researchers on this project will complete the HS training requirements before this research commences as well as any individuals who interact with human subjects or have access to their identifiable data. I understand that I am ultimately responsible for the safe conduct of this project and I will notify the Human Subjects Committee immediately in the following instances:

- A request for review and approval of all proposed modifications prior to implementation

- Report of any problems, adverse events, or unanticipated complications that may put subjects at increased risk of harm (e.g. mental or physical adverse events/reactions, breach of confidentiality)

- Report any other problems associated with the conduct of this research (e.g. non-compliance)

I agree to comply with all copyright and record retention requirements designated by University of California, UCSB Human Subjects Committee, Federal and State governments, and other organizations/institutions associated with this research, including funding organizations and sponsors.

STATUS

Approval Type:	B-Expedited	Date Research Can Begin:	3/5/2021
All Training Complete Date:	9/17/2020	Expiration Date:	3/5/2022
Approval Date:	3/5/2021		

CONFLICT OF INTEREST - Disclosable financial interests are:

1) No- Ownership interest, stock, stock options, or other financial interest related to the research, unless it meets all four tests:

- Less than $10,000 when aggregated for the immediate family and

- Publicly traded on a stock exchange and

- Value will not be affected by the outcome of the research and

- Less than 5% interest in any one single entity.

2) No- *Compensation related to the research, including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value, unless it meets both of the following tests:*

- Less than $10,000 in the past year when aggregated for the immediate family and the

- Amount will not be affected by the outcome of the research.

3) No- *Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.*

4) No- *Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research, regardless of compensation.*

List the Name(s) of Study Team Members who have Disclosable Financial Interests
(Including Lead Researcher, Co-Researchers, Research Personnel and, if applicable, Faculty Sponsor)

First Name	Last Name	Email	Phone

SUBJECT POPULATION:

Age range of subject population - Youngest: 1 *- Oldest:* 65

Anticipated number of subjects? 96

Do you plan to use human participants from any of the following populations?

Yes-Adults (18 years or older)	No-UCSB Students (18 years or older)	Yes-Minors
Yes-Cognitively impaired	No-Researcher's students	No-Researcher's subordinates
No-Wards of the state	No-Prisoners	No-Institutionalized
No-Pregnant	No-Other	

Describe the proposed subject population, including gender, race, ethnicity, language, and literacy.

We plan to recruit 48 family dyads (48 parents and 48 children) for this proposed study. One parent and one young child with autism per family will participate. Attempts will be made to recruit families across the United States that represent the racial/ethnic diversity of the country. All families will be English-speaking. Parents must be able to read and write.

Identify any criteria for subject inclusion or exclusion. If inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.

Inclusion Criteria:

Child participants must (a) be between the ages of 1.0 and 5.0 years (12 and 60 months), (b) have an existing diagnosis of autism spectrum disorder, and (c) have parent endorsements of significant language delay as a major area of concern.

Parent participants must be willing and able to read, complete intake and follow-up assessments, have regular access to an internet connected smartphone or tablet, complete the eight weekly PRT lessons, record and submit parent-child PRT videos, and review these videos on a weekly basis.

Exclusion Criteria:

Children with co-occurring significant medical conditions, seizures, and mental health concerns will be excluded.

Because all training materials will only be available in English for this initial trial, non-English speaking families will also be excluded. Families without access to a smartphone or tablet that can run the app and record video and those who do not have access to an internet connection will also be excluded.

RECRUITMENT METHOD:

Check which of the following recruitment tools will be used to recruit potential participants. Upload copies of recruitment materials (e.g. scripts, advertisements, flyers, letters) to the Attachments section:

No-SONA Pool

Yes-Website/Social Media Outlets

Yes-Email/Electronic Mailing List

Yes-Flyers or brochures

No-Letters

No-TV, radio, or print advertisements

Yes-Verbal (personal solicitation)

No-Telephone scripts

No-Other

Describe the process for how you will be recruiting potential participants. Include a description of how contact information will be obtained

Families will be recruited nationwide using targeted social media advertisements and postings on online forums (autism support forums, military family listservs), email announcements, social media groups (local Autism Society of America/Autism Speaks chapters), the UCSB Koegel Autism Center website, and word of mouth. See attachment section for the recruitment ad. Interested families who respond to our recruitment ad will be scheduled for a video conference or phone-based consent session.

LOCATION:

Select all study sites where the research will be conducted:

Yes-UCSB

No-International

No-Other university campus

No-Schools (public and private)

No-Private Institutions or locations

Yes-Other location (e.g. homes, online)

UCSB:

Research data will be analyzed at the UCSB Koegel Autism Center, housed with the Gevirtz Graduate School of Education at UC Santa Barbara.

Other location (e.g. homes, online):

Parents will use the project's smartphone application in their home in towns and cities across the United States. Entered data and video recordings will be sent to UCSB for analysis.

PURPOSE: *Provide a brief description of the purpose of the project in lay terms, including the specific study objectives, rationale, and hypotheses.*

The majority of families in the United States do not have access to adequate autism intervention services**.** The development of smartphone apps designed to train parents in these strategies may help. The objective of this proposed clinical translational research project is to develop and evaluate self-directed smartphone app-based parent education programs designed to facilitate mass dissemination of a well-established, evidence-based autism treatment (Pivotal Response Treatment). It is hypothesized that one of the apps, which will feature video self-modeling/ parent self-scoring components, will yield superior outcomes over the other app without these components.

SPECIFIC AIMS

1. Develop PRT smart-phone applications that combine existing instructional lessons and videos 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 app-based PRT programs as promising mechanisms to disseminate evidence-based autism intervention to the general public.
3. Determine if a PRT app with video self-modeling/fidelity self-scoring and individualized feedback components yields superior gains in parent fidelity and child outcomes over the basic PRT app without this functionality as a means to evaluate mechanisms underlying rapid learning and mastery of PRT strategies.

METHODS:

Check which of the following data collection tools and/or methods you plan to use:

Yes-Questionnaires/surveys	No-Interviews	No-Focus groups
No-Observation	No-Audio recording	Yes-Video recording
No-Photography	No-School records	Yes-Personally identiable info
No-Identifiable health info	No-Other	

Check which of the following biomedical procedures you plan to use: N/A

No-Physical tasks	No-Medical equipment	No-Genetic testing
No-Biological specimens	No-Physiological Intervention	No-Other

PROCEDURES:

Does this project involve active deception? Active deception occurs when an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research.

-No

Does this project involve incomplete disclosure? Incomplete disclosure occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research.

-No

Describe your study procedures in detail of how the research will be conducted. Include information about all study procedures (e.g. all interventions/interactions with subjects, data collection procedures) and follow-up procedures. Include the number, duration, and frequency of sessions to be completed with the participants. Upload copies of all study materials to the Attachments tab.

Overview

This proposed project aims to conduct a pilot randomized clinical trial to investigate the feasibility, utility, and preliminary efficacy of two versions of a self-directed, smartphone app-based parent education program to teach Pivotal Response Treatment to target core social communication vulnerabilities (social engagement and language use) in young children with autism. A PRT Manual is included in the attachments if HSC reviewers would like more information on this treatment model. The programs will both focus on training parents in the well-established, evidence-based, manualized PRT early autism intervention, with the following manipulation:

1. **BASIC PRT PROGRAM:** Parents complete 8 weekly training PRT training lessons within the app and then use the app to record and submit a 5-minute video administering the PRT intervention with their child doing PRT after each lesson. **Parents will then watch their video performance, but they will not score their own performance or receive individualized feedback based on this performance.**

2. **ADAPTIVE PRT PROGRAM:** Parents complete 8 weekly training PRT training lessons within the app and then use the app to record and submit a 5-minute video administering the PRT intervention with their child doing PRT after each lesson. **Parents will then review their video and self-score their PRT performance using a built-in fidelity scoring feature within the app. At the end of scoring, the program will indicate areas of strength/weakness and provide feedback to improve their future PRT performance.** A depiction of a PRT lesson and the app are in the attachment section.

This adaptive program is intended to remedy identified shortcomings of standard self-directed training programs with the introduction of video self-modeling/individualized instructional components that allow parents to (a)

regularly record and review their own parent-child treatment videos, (b) self-score their performance for PRT fidelity of implementation, and (c) access an adaptive curriculum of lessons based on identified fidelity shortcomings or parent-selected review topics/questions.

Type of Clinical Trial

This proposed project will utilize a double-blind randomized clinical trial design to compare the two PRT mobile applications on parent and child outcome measures. Parents and researchers will both be blinded to the PRT app condition of each family.

Research Partners

Our research team will be partnering with Novacoast, Inc., a Santa Barbara software company specializing in secure, cloud-based software-as-a-service solutions. We will combine our existing online PRT curriculum with their encrypted video upload and fidelity coding software into a single user-friendly smartphone/tablet application. Videos that are uploaded by participant families are automatically uploaded to secure Box cloud folders.

Procedure

After completing informed consent, parents complete an initial online battery of intake assessments (see measures below). These online surveys are completed through a provided link to the online test companies' secure, encrypted testing website, which the study researchers can later access using a username and password Parents will also complete demographic questionnaires through an in-app link to a secure UCSB Qualtrics form. Personally Identifiable Health Information will include parent names, child names, child autism and co-occuring disorder diagnoses, email, phone, zip code, city, and state. Families will be randomly assigned to adaptive or standard (control) PRT application groups for the 8 week intervention period. Parents will be unaware of group assignment and will be asked to video record and upload a weekly 5-minute parent-child PRT session after each lesson. Research assistants (also masked to participant study condition) will use Noldus Observer coding software to score PRT fidelity of implementation (Primary Outcome) and child social communication behaviors (Secondary Outcomes): prompted and unprompted words, eye contact, and directed positive affect for each participant family's submitted videos (intake, after PRT lessons 1-8, and at follow-up 2 months after the final lesson). Online child development surveys (Secondary Outcomes) will also be administered at intake and follow-up (2 months after completion of the last PRT lesson).

Pivotal Response Treatment is an evidence-based autism intervention that combines motivational strategies and behavioral principles into a single comprehensive model (Gengoux et al, 2019; Verschuur et al, 2014). It leverages child selected/preferred activities, task variation, clear learning prompts, contingent reinforcement of language attempts, logically related reinforcers, and a combination of mastered and new learning tasks to improve child language use and social engagement. It is a play-based approach that is delivered in natural environments and emphasizes parent education (Verschuur, Huskens, & Didden, 2019). A PRT manual and fidelity scoring guide are included in the attachment section.

The app-based PRT parent education program will consist of eight weekly 20-minute lessons. Each module will be entirely self-guided and progressively build upon skills learned in prior lessons. All informational slides will be accompanied by video examples to model proper use of PRT strategies. Brief multiple-choice quizzes and self-assessments will also be incorporated to assess comprehension of the material. Parents will be encouraged to incorporate treatment strategies into their daily routines, interactions, and play activities on a regular basis. The planned app format is provided in the following table:

App Format & Sequence

Title Page

Welcome splash screen

Program Overview, Consent for Research

Provides a description of the app, the nature of the research, and provides the informed consent form. Also provides messaging link to ask questions to the research team or schedule a phone conversation prior to consenting.

Registration Page

Participants are asked to complete demographic questionnaires and are sent links to complete online intake assessments.

Tutorial of App

Participants are provided with a brief video and visual tutorial of the app format so that they know what to expect and how to navigate through each lesson (Lesson, Video Capture, Review Sequence)

Lesson Format (20 mins)

- Intro Video
- Overview Slide
- Narrated Content Slides
- Demonstration Videos
- Additional Narrated Content Slides
- Additional Demonstration Videos
- Comprehension Check with Multiple Choice Items
- Summary Slide

Video Capture (5 mins)

- Video capture tutorial with visuals for positioning the shot, capturing faces and activity
- 5-minute video capture of parent & child doing PRT
- Video check/confirmation questions (parent & child both on screen, child not disruptive)

Video Review (10-15 mins; can be done immediately after capture or saved for a later time)

- Tutorial on scoring PRT fidelity *(adaptive apt only)*
- Replay of video
- During video, parents will pause after each PRT trial, score for presence/absence of each PRT component *(adaptive apt only)*
- At the end, the program will provide a performance summary with percent use of each treatment component *(adaptive apt only)*
- The app will offer a link to trouble-shooting guidance/frequently asked questions

The content of the eight PRT lessons is summarized below:

Summary of the Eight App-Based PRT Lessons

The ABCs of PRT

An overview of PRT and its underlying behavioral and motivational strategies.This lesson focuses on

understanding the antecedent, behavior, consequence sequence of PRT learning opportunities and briefly describes all components

Child Choice & Task Variation

The concept of following the child's lead, varying the activity, and using their preferred activities and interests as the focus for PRT learning opportunities

Child Attention & Clear Opportunities

The importance of obtaining the child's attention prior to delivering a clear, simple learning prompt

Contingency & Reinforced Attempts

The concept of immediately and contingently reinforcing any reasonable effort (not just perfect responses) to a prompted language attempt.

Natural Reinforcement

Use of logically related, natural reinforcers that are directly related to the child's verbal response.

Maintenance & Acquisition Tasks

A blend of easy, previously or nearly mastered learning opportunities to maximize motivation with more challenging, new concepts to promote more complex language acquisition

Social Activities & Reinforcement

Using social activities based on existing child interests to increase social motivation and engagement over time

Summary and Frequently Asked Questions

Reviews common questions and concerns raised by parents enrolled in PRT trials. Addresses strategies to respond to a lack of child responsiveness, slower than expected language development, and the presence of behavioral challenges.

Data Collection: Parent-Child Video Probes. At intake, parents will be instructed to submit a 5-minute video of a parent-child interaction using a child's preferred toys and activities. Parents are asked to play with their child while attempting to elicit as much social engagement and communication as possible. After completing each online PRT lesson, parents will be instructed to submit a 5-minute video capturing their use of PRT strategies with their child, again using preferred toys and activities. Videos will be recorded and uploaded through the smartphone app. Because the program is designed to be an autonomous training program, families will not receive feedback on their performance from our research team. Parents in the standard PRT app condition will then watch their own video. Parents in the adaptive condition will be asked to watch their own video and score their own PRT fidelity using the app's built in scoring functionality. Specifically, parents will be instructed to pause the video after each PRT learning opportunity and tap buttons to indicate the presence or absence of core PRT components (see below). This video self-modeling exercise will allow parents to reflect on their own progress and serve as a guide to identify areas for future practice. In both conditions, within app upload of each weekly video is required in order to unlock access to the next lesson in the online PRT curriculum.

Data Collection: Standardized Assessments. At intake, parents will also complete digital versions of standardized survey measures (secondary outcome measures described in the study variable section below) through emailed weblinks to testing company secure, encrypted websites. Assessments will be re-administered 2-3 months after completion of the trial (and 4-5 months from the intake timepoint), allowing families to provide additional PRT intervention on an independent basis for 2-3 additional months.

STUDY VARIABLES

Parent Fidelity of Implementation Data (Primary Outcome). Video submissions will be independently coded by trained research assistants using Noldus Observer XT software to monitor improvements in parent Fidelity of Implementation (FOI) over the course of the program. Each learning opportunity will be scored on a trial by trial basis. Parents must demonstrate each PRT component (described below) in 80% of trials to meet FOI:

Behavioral Coding: Fidelity of Implementation

Child Attention

The parent must have the child's attention (on the stimulus or the parent) prior to presenting an opportunity.

Clear Opportunity

The parent's question/instruction/opportunity for the child to respond must be clear and appropriate to the task.

Child Choice

The parent should follow the child's choice with tasks and activities. However, the parent must always assume control should the child engage in dangerous (e.g. self-injury) or inappropriate (e.g. destroying property) activities. If child is not showing interest in the current task, parent should attempt to change the activity.

Task Variation

The parent must vary the activities/prompts used across the PRT session probe.

Contingency

The parent must provide reinforcement contingent upon child's language attempt. That is, the parent' behavioral response (i.e. giving the child a toy) must be dependent upon the child's verbal response (i.e. saying "toy").

Natural Reinforcement

The parent must provide reinforcement that is directly and logically related to the child verbal request (e.g. the toy or activity being requested). Use of non-related reinforcement (stickers, edibles) is inappropriate

Reinforced Attempts

The parent should reinforce any goal-directed attempt to respond to questions, instructions, or opportunities. Although an attempt does not necessarily need to be correct, it has to be reasonable.

Maintenance & Acquisition Tasks

The parent should provide a combination of easy and more challenging task prompts

Child Social Communication Behaviors. Videos will be coded for the following child social communicative behaviors: vocalizations, eye contact, and positive affect. These behaviors were selected due to prior research indicating that these social communication skills are particularly important for development and may improve following PRT intervention (Bradshaw, Koegel, Koegel, 2017; Koegel, Vernon, Koegel, 2009; Vernon, Koegel, Dauterman & Stolen, 2012). Interrater reliability, and kappa estimates will be calculated to ensure consistent coding across research assistants. Video segments in which the child is off-screen/blocked by a parent will be eluded from analysis.

- **Child Vocalizations** are an indicator of attempts to use verbal communication and are defined as any verbal communication attempt that includes both intelligible words and directed word-attempts and vocalizations. This variable will be divided into the subcategories of *prompted vocalizations* (i.e. responses to a parent's verbal prompt) and *unprompted vocalizations* (i.e. spontaneous use of language without parent prompts). Undirected, scripted, and self-stimulatory vocalizations will be coded separately.

- **Child Eye Contact** is a measure of social attention and engagement and is defined as the child looking toward the parent's eyes.

- **Child Positive Affect** is another measure of social attention and engagement within each session and is defined as smiling or laughing. It will be coded on a continuous basis**.**

Standardized Survey Measures. Digital versions of the following survey measures will be used for baseline participant characterization purposes in both phases. In Phase 2, these measures will also be administered at a 6-month follow-up time-point to obtain preliminary child outcome information. **See attachment section to view these scales.**

- ***Social Responsiveness Scale, Second Edition*** (SRS-2; Constantino & Gruber, 2007). The SRS-2 is a caregiver-completed measure of a child's autism symptom severity. Parents will complete a digital version of the Toddler SRS-2.

- ***Vineland Adaptive Behavior Scales, Third Edition*** (Sparrow, et al, 2016). The Vineland-III is a caregiver-completed measure of adaptive functioning in children.Parents will complete digital versions of the Communication and Socialization domains of the Vineland-III Parent/Caregiver Rating Form.

- ***MacArthur-Bates Communicative Development Inventory*** *(CDI), Level I Short Form* (Fenson et al., 2000). The MacArthur-Bates CDI is a caregiver-reported measure of child expressive vocabulary use. Parents will complete a digital version of the CDI to obtain information on reported word usage and understanding.

Parent App Use Data: The amount of time that parents spend using the PRT apps (i.e. engaged in new lessons or reviewing old lessons), along with latency between completed lessons will be analyzed as potential predictors of outcome.

Parent Perceptions of Acceptability & Effectiveness Data. Feedback information will be obtained to assess parents' satisfaction with the program, confidence in their therapeutic skills, and perceptions of child behavior change. parents in both phases will be asked to complete an in-app exit survey. This survey will consist of both quantitative and qualitative elements. They will first be asked to respond to a variety of statements using a scale of 0 (Strongly Disagree) to 5 (Strongly Agree). Items assessed for in this measure will include statements such as:
"Over the course of the program, I have seen my child's language skills improve,"
"Over the course of the program, I have seen my child's social engagement improve,"

"I have a clear understanding of Pivotal Response Treatment component of _____,"

"I would recommend the course to another family."

Parents will also be asked to provide written feedback on their experience of the course and suggestions for improvement. This information will help identify potential barriers to program completion and will be used to modify the program at the end of both phases:

1. In your opinion, what were the most positive aspects of the program?
2. In your opinion, what were the most negative aspects of the program?
3. Each weekly lesson had informational slides, videos, and quizzes.What did you think about the format of the weekly lessons? Would you have liked to see more or less of any of these components?
4. What else could we have added to the lessons to make a concept clearer or easier to understand?
5. What are your thoughts about the time requirements and pacing for this program? Would you have liked a shorter or longer program? Would you have liked more or less detailed lessons?
6. What was your experience recording and uploading videos with your child?
7. What was your experience reviewing your videos and scoring the PRT concepts?
8. Do you have any suggestions for improving the video upload or review process?

Data Storage and Reporting: Data will be stored on encrypted folders on Box or on REDCap, which is a secure research database software program. The proposed trial will be registered with clinicaltrials.gov. As part of the informed consent process, participants will consent to allow their deidentified data (no videos) to be shared with National Database for Autism Research (NDAR). Dr. Vernon will hold primary responsibility for publication of the results of the study and will work closely with other research team members to ensure timely dissemination of findings.

Will participants be compensated (money, course credit, any other incentive) for their participation? -Yes

Describe the plan for compensation of the participant and prorating if an individual withdraws from the study. Will social security numbers be collected? If yes, please include in consent form.

No

Families will be compensated with $25 for completing all intake assessments and a preliminary parent-child interaction video, up to $40 for recording and uploading parent-child PRT videos after each of the eight lessons ($5 per video), and $25 for re-completing assessment measures and a final parent-child PRT video 2-3 months after completing the final lesson, with total compensation of $90 per family. Families who do not complete all research phases will be compensated for the phases they did complete (prorated compensation). Families will be paid through secure electronic transfer (Paypal, Venmo).

RISKS:

PSYCHOLOGICAL: *Describe psychological risks (psychological damage, embarrassment, discomfort, forced awareness).*

Risk:	*Safeguard:*
While the vast majority of children find the motivational intervention highly enjoyable, a small percentage of participants may be momentarily frustrated when encouraged to use language to obtain desired items and activities. Parents may become concerned, distressed, or anxious if they do not master the lessons as quickly as they anticipated, if their children do not respond to their playful intervention bids, and/or if their children do not make the progress parents anticipated in language or social engagement domains.	These concerns constitute no more than minimal risk and are comparable to everyday experiences by families who seek out autism therapy. The intervention (Pivotal Response Treatment) is designed to be socially engaging and motivational in nature. It does not require perfect language requests in order to reinforce child language with desired toys and actvities, tasks are varied frequently to ensure that motivation is maintained, and free access to activities is initially provided. Parents are encouraged to stop the session if the children are having particular difficulty on a given day. Participants can withdraw at any time without penalty. For parents, the PRT app lessons will include troubleshooting and frequently asked question features designed to help parents learn and master missing intervention components. The lessons will also normalize the experience of having children be slow to respond or make progress and will guide parents to additional strategies for further promoting language and other developmental gains. Fears of a lack of developmental progress would be present in parents even outside the context of this research project, while participation actually gives them actionable steps to improve their outcomes

PHYSICAL: *Describe physical risk (injury, exposure to violence, medical equipment).*

Risk:	*Safeguard:*
None anticipated	NA

CONFIDENTIALITY/PRIVACY: *Describe how privacy will be protected and confidentiality will be maintained (invasion of privacy, breach of confidentiality, exposed to criminal or civil liability, loss of job/employability, mandatory reporting to outside entities)*

Risk:	*Safeguard: Describe how privacy will be protected and confidentiality will be maintained.*
There is a slight risk of identifiable information being exposed. Parent PRT improvement data and feedback survey questions pertaining to app usability/suggestions for improvement will be shared with Novacoast to further revise the app.	The informed consent process serves as the terms and conditions document for use of the app, outlining how their data can and cannot be used. Parents are informed that their de-identified usage data and feedback will be used to shared with Novacoast to improve the app. Novacoast is not permitted to use the usage data for marketing or other research purposes. All participant information/video will be encrypted by the app prior to upload and are stored on the encrypted Box folder or REDCap database owned and managed by UCSB. All researchers are HIPAA trained and informed of privacy procedures.

DATA STORAGE: *Describe how and where data will be stored. Include the types of devices (e.g., computer, tablet, Cloud service storage, etc.) used to store the information and if the devices are encrypted and/or password protected.*

Risk:	*Safeguard: If identifiable data (i.e., information and/or biospecimens) will be collected, include the disposition (for example, if identifiers might be removed or retained, how the data will shared, stored, archived, etc.) NOTE: Consent form(s) must include the storage and disposition of the data.*
All participant information/video will be encrypted by the app prior to upload and stored on the encrypted Box folders. Participant videos will be stored indefinitely. However, participants may request that these videos be deleted at any time. Identifiable information (e.g. contact information) will be stored separately from research data. A code will be assigned to link the data back to the subjects.	All participant videos and identifying information will be stored on encrypted BOX or REDCap databases. All staff must complete HIPAA and Human Subjects training prior to

	receiving data access. Staff access to the server is restricted based on project roles and access privileges are reviewed quarterly.

AUTONOMY: *Describe the risk to autonomy (incentives coercion, economic, use of own students/staff/friends):*

Risk:	*Safeguard:*
Financial incentives may coerce participants to enroll. Participants may fear their app usage data is being used by Novacoast for non-research purposes (marketing)	Incentives are reasonable based on time involved ($25 for intake questionnaires and $5 per submitted parent-child video. Parents are also receiving access to a highly effective autism intervention, so the cash incentive is unlikely to be the primary motivator for participation. Novacoast will not use the acquired data for purposes other than this research project.

OTHER: *Describe any risks not listed above.*

Risk:	*Safeguard:*
None anticipated	NA

CONSENT PROCESS: Describe procedures for obtaining informed consent. Include who will be responsible for seeking consent, how, when, and where consent will be obtained. If research will involve a non-native speaking population or an international component, describe the investigator(s) linguistic proficiency and/or how the consent documents will be translated in the subject's native language. Describe the measures taken to ensure subjects are informed about the research and how the appropriateness of the consent process will adhere to cultural standards.

When families respond to recruitment advertisements expressing interest in participation, they will be scheduled for a consent video conference or phone session with a member of the UCSB research team. Prior to or during this meeting, they will be asked to download the smartphone app and follow along with the in-app written consent information. This information will also be emailed to them. Potential participants will first be presented with a brief summary of the project and a timeline. Participants then have the option to continue to a hear more detailed informed consent information or decline participation. After hearing about the project from a member of the UCSB research team and reading through the informed consent information, participants have the option to digitally sign the consent form, read through frequently asked questions, and ask the research team questions, or have additional time to think about it.

Waiver of Written Documentation

Are you requesting a waiver of written documentation? Consent forms must be signed unless a waiver of written documentation (i.e. physical signing of the consent form) is requested, justified and approved.

-Yes

Select which of the following criteria applies to your project:

No-The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research AND the consent document is the only record linking the subject with the research.

Yes-The research presents no more than minimal risk and involves procedures that do not require written consent when they are performed outside of a research setting.

No-The subjects are members of a distinct cultural group or community in which signing forms is not the norm.

Select the consent process that you propose to use in this study as an alternative to written informed consent:

No-Oral Consent

Yes-Information Sheet

No-Other

Waiver of Consent:

-No

Are you requesting an alteration or a full waiver of informed consent? If the consent process omits or alters one or more of the required elements (see 1-10 below) of informed consent, then a waiver of consent must be requested, justified and approved. -No

Child Assent and Parental Permission

Will you be requesting a waiver of assent for children aged 17 or younger?

-No

Will you be requesting a waiver of written parental or guardian permission?

-Yes

Which type of waiver applies to your project?

I am obtaining parental or guardian permission, but not collecting signed consent forms

Select which of the following criteria applies to your project:

Yes-The research presents no more than minimal risk; it is not practicable to conduct the research without the waiver or alteration; waiving or altering the permission will not adversely affect the subjects' rights and welfare; and pertinent information will be provided to the subjects later if appropriate

No-The research will be conducted by or subject to the approval of state or local governmental officials; the project is designed to examine (i) public benefit of service programs, ii) procedures for obtaining benefits or services under those programs; iii) possible changes in or alternatives to those programs or procedures; or iv) possible changes in methods or levels of payment for benefits or services under those programs AND it is not practicable to conduct the research without the waiver or alteration.

No-Written parental or guardian permission is not a reasonable requirement to protect the subjects (e.g. neglected or abused children) AND there are appropriate mechanisms for protecting the children who will participate as subjects in the research are substituted AND the waiver is not inconsistent with federal, state, or local law.

Provide a substantive rationale for this request to waive written parental permission:

The study will be conducted completely online and participants will not meet in person with the research team; therefore, an electronic consent form with digital signature will be provided.

I	WR	NA	ELEMENTS OF INFORMED CONSENT *I = Informed Consent* *WR = Waiver Requested* *NA = Not Applicable*	
Required Elements				
X			1.	Investigator's name, phone number, & email address.
X			2.	A description of the nature & purpose of the study.
X			3.	Description of procedures to be used and the expected duration of the subject's participation.
X			4.	A statement describing the extent to which and how confidentiality of records identifying the subject will be maintained.
X			5.	A statement that identifiers might be removed from identifiable private information or identifiable biospecimens and after such removal, the information or biospecimens could be used in future research without additional informed consent (if applicable). OR, a statement that information or biospecimens, collected as part of this research, even if identifiers are removed, will not be used for future research studies.
X			6.	A description of any attendant discomforts & risks reasonably to be expected or (rarely) that there are no foreseeable risks.
X			7.	An explanation of any benefits to the subjects or society reasonably to be expected (payment/class credit is not considered a benefit).
X			8.	An offer to answer any questions concerning the study.
X			9.	An instruction that participation is entirely voluntary, & consent to participate may be withdrawn at any time without prejudice.
X			10.	Human Subjects Committee contact information.
Optional Elements:				
X			11.	Approximate number of subjects involved in the study.
X			12.	Any payment, reward, or cost for participation. Include how payments or rewards will be prorated if the subject withdraws.
		X	13.	If extra credit for a class is given, an explanation of the non-research alternative available to earn equivalent credit.
If applicable, make a selection from the below items				
X			14.	Warning of UCSB's mandatory child abuse reporting for studies through which the Investigator might gain knowledge of child abuse.
X			15.	An instruction that either the investigator or the subject may terminate the subject's participation at any time.
X			16.	For any study involving more than minimal risk, which may result in injury, include the following standard language: If you are injured as a direct result of research procedures, you will receive reasonably necessary medical treatment at no cost. The University of California does not provide any other form of compensation for injury.
X			17.	The disclosure of any alternative procedures, drugs or devices that might be advantageous to the subject; their relative risks & benefits.
X			18.	An explanation of any drug or device to be utilized, & any foreign substance to be administered.
X			19.	Identification of procedures, drugs, or devices that are experimental.
		X	20.	A statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus if the subject is or may be, pregnant) which are currently unforeseeable.

X			21.	Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
		X	22.	A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
		X	23.	For any study which may result monetary gain for the researcher, add the following statement: The study investigator has a financial interest in this research and may benefit monetarily from this study. You may ask your investigator for more information on his or her interest.
		X	24.	If samples will be taken for research and development purposes not related to the subject's treatment or condition, include the following standard language: Samples taken during this study may be used for research and development purposes not related to your treatment or condition. You will not have any property rights or ownership interest in products or data which may be derived from your samples.
X			25.	A statement whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
		X	26.	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.
		X	27.	One or more study team members have been listed with a disclosable financial interest.

CONSENT FORMS:

Form Name	Form Type	Description
Parent Consent	Model Consent	Parent Permission

RISK/BENEFIT ANALYSIS: Activities involving human subjects can only be approved if the expected benefits outweigh the risks and activities do not pose any unnecessary risks to subjects.

BENEFITS: *Describe benefits, if any, to the subjects, to the class of subjects, to society, and to advancement of knowledge. If there are no direct benefits anticipated for the subjects, please state as such.* **Do not include compensation as a benefit.**

It is anticipated, though not guaranteed, that the participant children with ASD will exhibit increases in their use of appropriate social-communication skills. It is also anticipated that participant parents will acquire effective intervention skills. Disparities in access to services for children with ASD are an area of increasing concern for the field of autism research, and this study will examine whether an smartphone app-based intervention model can help to provide quality services to those who might not otherwise receive them.

RISK-BENEFIT ANALYSIS: *Explain why any risks to the study are reasonable in relation to the potential benefits to subjects and/or society.*

There are minimal risks associated with participation in this study. The potential to improve treatment access and outcomes for many children with ASD represent substantial benefits.

UPLOADED DOCUMENTS:

Document Type	File Name	Upload Date
Instrument	SRS-2 Preschool Form.pdf	7/10/2017
Instrument	Vineland Items.pdf	10/17/2018
Instrument	MCDI.pdf	10/17/2018
Instrument	PRT Fidelity Guide 2019.doc	12/18/2019
Recruitment	Recruitment Ad - PRT Smartphone App.docx	2/20/2020
Images	PRT App Sample Screenshots and Features.pdf	12/19/2019
Other	Week 2 Module.pdf	4/28/2017
Other	PRT Manual Final.pdf	12/18/2019
Scientific Merit Review	IRB Scientific Review Form - DoD PRT App Grant.pdf	3/9/2020

Progress Report:

Describe your experience with the use of human subjects in this project. Include how many subjects have been used, a summary of the research to date, and any other pertinent information (e.g. publications or presentations of this data)

Research activities to date have included recruiting and training study personnel, creating modules for the PRT application and coordinating with application developers, planning for recruitment, and preparing to create the online RedCap database to securely store PHI and questionnaire data. In response to the COVID-19 pandemic, all study coordination has occurred virtually. There have been no human subjects recruited or enrolled yet (anticipated for later this year)

Have there been any complaints, complications, or unexpected outcomes? -No

Has the research resulted in any publications or presentations within the last year? -No