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TITLE: Randomized Controlled Trial of Telehealth-Enabled Versus In-Person Parent-Mediated Behavioral Treatment for Challenging Behaviors in Autism Spectrum Disorder

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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	3
2. Keywords	3
3. Accomplishments	3
4. Impact	7
5. Changes/Problems	7
6. Products	8
7. Participants & Other Collaborating Organizations	9
8. Special Reporting Requirements	10
9. Appendices	10

1. INTRODUCTION:

The overarching goal of this research is to address disparities in access to critically needed healthcare for families of children diagnosed with autism spectrum disorder (ASD), particularly those who live in rural and medically underserved communities. Specifically, our project will directly address whether remote delivery of parent-mediated behavioral therapy, based on the principles of applied behavior analysis (ABA), is more efficient and results in less stress on the family compared to traditional in-person parent-mediated behavioral therapy for the treatment of challenging behavior in children with ASD. This study holds great promise to advance understanding in the field of ASD with respect to the long-term effectiveness, feasibility, and acceptability of implementing parent-mediated behavioral therapy via telehealth for challenging behavior in children diagnosed with ASD.

2. **KEYWORDS:** Autism spectrum disorder, challenging behavior, telehealth, applied behavior analysis, parent stress, randomized controlled trial

3. ACCOMPLISHMENTS:

○ What were the major goals of the project?

- Major Goal 1: To define the needs and barriers to providing parent-mediated interventions for challenging behaviors in children diagnosed with ASD by conducting interviews of parents, treatment providers, and insurance stakeholders, in partnership with a caregiver, provider and payer advisory board.
 - Activities for this phase of the project began on 5/1/22 and were completed on 4/30/23.
- Major Goal 2: To determine whether parent-mediated behavioral therapy for challenging behaviors exhibited by children with ASD may be more efficient and results in less stress on the family when caregiver coaching is delivered via telehealth compared to traditional in-person caregiver coaching.
 - Activities for this phase of the project are scheduled to begin on 6/1/23.

○ What was accomplished under these goals?

1) major activities;

- Major Task 1 has been completed
 - Job descriptions for research staff were generated
 - Research staff were hired and trained
 - Space for staff was allocated
- Major Task 2 has been completed (subtasks 1 and 2)
 - Regulatory documents and research protocols for stakeholder interviews were prepared
 - The consent form and human subjects protocol stakeholder interviews was finalized
 - Eligibility criteria, exclusion criteria, and the screening protocol for Study 1 were refined
 - The IRB protocols at Stanford University and WCG were submitted and approved
 - The USAMRDC (ORP/HRPO) protocol was submitted and approved
 - The study was registered on Clinicaltrials.gov
 - The annual IRB report was submitted to WCG and approved

- Major Task 3 has been completed (subtasks 1 and 2)
 - We recruited 10 caregivers, 10 providers and 5 payers (n=25) and completed interviews with 9 caregivers, 9 providers, and 4 payers (Total n = 22). Each interview was administered over Zoom using our IRB-approved Interview Schedule, with interviews lasting 1-2 hours.
 - All interviews have been transcribed using transcription software
 - The major themes and subthemes have been identified and synthesized
 - Study modifications have been generated per discussion with the study team
 - Modifications of the treatment protocol that were needed for the clinical trial protocol (Study 2) have been determined
 - All protocols for the Study 2 have been modified according to stakeholder feedback
 - Six Stakeholder Board meetings were held between October 2022 and April 2023. All 10 members of the Stakeholder Board participated and provided feedback on Study 2 procedures

- Major Task 4 (subtask 1) has been completed
 - All treatment protocols have been developed and manualized
 - All assessment measures have been finalized
 - iPads for use by participants have been purchased and encrypted
 - A flow chart for all study steps, web data collection and database requirements has been created
 - Changes to the functional analysis and treatment protocols have been made following feedback from the Stakeholder Board. Measures have been refined and additional outcome measures have been added to the assessment battery.

2) specific objectives

- The objectives of the next phase will be:
 - To submit all protocol changes to the IRB for approval
 - To start recruitment of participants for the randomized controlled trial (Study 2) once all protocol changes have been approved

3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative);

- The following themes were identified from the caregiver interviews (see Appendix 2):
 - **Theme 1: Behavioral concerns.** Caregivers provided detailed descriptions of their child's behavioral concerns and commented on how these behaviors impacted family quality of life. These behavioral concerns included anxiety, challenging behavior, social communication difficulties, sleeping concerns, feeding concerns, toileting concerns and repetitive and stereotyped behavior.
 - **Theme 2: Barriers to accessing ABA services.** Caregivers commented on the limited availability of providers in their area and being placed on the wait list at several agencies, in some cases for several years. Some caregivers described how the providers they had contacted did not return their calls, despite repeated attempts to schedule an evaluation. Indeed, some caregivers reported that they had experienced significant delays between the initial ABA assessment and starting ABA treatment. Caregivers also commented on the lack of experienced ABA providers available in their area, citing the need for better training of Registered Behavior Technicians (RBTs) and other agency staff. Some caregivers talked about having to travel long distances to receive ABA services, reporting that they sometimes spent significant periods of time in the car, often stuck in traffic. Furthermore, caregivers described how travelling to and from appointments exacerbated their child's challenging behavior, thereby impeding their child's ability to receive therapies/services. Finally, caregivers described the impact of behavioral treatment on their job and their spouse's job, stating that managing their child's schedule while holding down a job was extremely stressful.

- **Theme 3: Satisfaction and experience with ABA therapy.** Caregivers were generally satisfied with the ABA services they had received. However, some caregivers talked about significant turnover in staff at some agencies, particularly with respect to turnover in RBTs working in the home setting and at some clinics which could result in gaps in care. Some caregivers talked about the need to incorporate ABA more effectively in school settings given that the majority of services were focused on in-home care for younger children or at clinics. Caregivers also commented on the disruption that treatment could cause on daily family life such as scheduling family meals and events around treatment sessions and ensuring that other family members were available to care for younger siblings. Caregivers also experienced difficulties communicating therapy goals with their ABA provider. Finally, caregivers talked about the challenges of coordinating schedules for treatment sessions.
- **Theme 4: Cost of services/insurance.** Caregivers noted the significant financial impact of receiving ABA services and the issues surrounding insurance claims that could put a significant burden on the family. Caregivers also noted how confusing and stressful it was to contact their insurance company. One caregiver also mentioned that many families were unable to receive services because they didn't have insurance coverage and that there was a shortage of providers that accepted Medicaid.
- **Theme 5: Benefits/drawbacks of telehealth service delivery models.** Caregivers reported accessing a variety of telehealth service delivery models including receiving telehealth services administered directly to their child via videoconference, accessing services that involved an RBT being remotely supervised by a BCBA, as well as receiving parent training to manage their child's behavior remotely by a BCBA. Several mothers commented on the need to understand which telehealth model was the best for their child given their child's age and skill level. For example, several mothers were skeptical about whether services could be delivered to their child directly via telehealth, given their child's ability to pay attention on the computer, the potential for distractions in the home, and the potential for connection and technology problems. Several mothers talked about the benefits of receiving services via telehealth relative to traditional in-person services. Indeed, several caregivers who received services via telehealth pointed out that their therapist was more likely to be available and would have more time to engage remotely with their child than if they had received in-person services. Furthermore, caregivers commented that gaps in care may be less likely to occur if the therapist delivered services via telehealth. Caregivers also talked about reducing technology, cost, and infrastructure barriers related to increased access to telehealth.

Data from the payer interviews indicated that payers were optimistic about the provision of treatment via telehealth and noted the benefits of the service delivery model for enhancing access to care, both in rural and metropolitan areas. The payers noted that their priority was to expand the research literature to better understand patient outcomes via telehealth service delivery models. Payers specifically requested large randomized controlled trials to compare the effectiveness of the different telehealth service delivery models to in-person services across all service types (e.g., assessment, parent coaching, direct treatment). Payers were also interested in better understanding what patient profiles would benefit from a telehealth service delivery model.

4) other achievements

- We have created a study website to facilitate enrollment of study participants.
- All study procedures and measures have been finalized and are ready for piloting.

- **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?**
 - We plan to begin recruitment for the randomized controlled trial. This will involve screening, recruitment, and consent of participants. We will evaluate and assign each participant to one of the three randomized groups and assess participants at the each timepoint. We plan to coordinate with the Data Core at SCCR for monitoring data collection rates and data quality. We plan to complete enrollment for approximately 25% of the study sample.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**
 - *Nothing to Report.*
- **What was the impact on other disciplines?**
 - *Nothing to Report.*
- **What was the impact on technology transfer?**
 - *Nothing to Report.*
- **What was the impact on society beyond science and technology?**
 - *Nothing to Report.*

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**
 - We recruited 5 payers for the interviews rather than the 10 originally planned. This was because the payers we recruited represented both vendor-ownership relationships and vendor relationships with over 30 healthcare plans in more than half of the states across the country. The 5 payers also represented multiple types of healthcare plans, including commercial, Medicaid, and self-funded plans and advised on healthcare policy across these plans.
 - Following discussions with our Stakeholder Board, we have decided to recruit participants from a single site that covers a larger area rather than have two separate smaller sites. Specifically, we plan to recruit participants for Study 2 from a single site that covers 12 counties in New Mexico. The reasons for this change are as follows:
 - Recruitment of participants from a single site that covers a larger area in New Mexico will allow us to enroll participants from a more diverse range of backgrounds and ethnicities, as well as families who live in rural areas. Across the 12 counties in New Mexico, 30.1% of the population live in rural areas and 47.6% of the population are Hispanic/Latino.
 - We will no longer have to control for potential differences in demographic variables at the two sites.

- We have identified study clinicians who have similar experience and training and are willing to travel within the 12 counties specified at the single site.
 - The change from two sites to a single site will enable us to transfer the sIRB from WCG to Stanford University.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
 - We anticipate that moving the sIRB to Stanford may result in a delay to the enrollment of potential participants for Study 2. We will be training all study staff and piloting the procedures and measures while we are awaiting approval from Stanford IRB.
- **Changes that had a significant impact on expenditures**
 - The costs associated with having an external sIRB at WCG were not anticipated or included in the initial budget. We have worked with our departmental finance support staff to develop a plan to manage the financial implications of the unexpected sIRB costs, including defraying the costs as much as possible by combining anticipated protocol changes into one IRB submission. Moving the sIRB to Stanford will avoid further external sIRB costs moving forward.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
 - Nothing to Report.
- **Significant changes in use or care of human subjects**
 - Nothing to Report.

6. PRODUCTS:

- **Publications, conference papers, and presentations.**

Pollard, J.S., Solis, M., Bujanda-Rodriguez, A. & Hall, S.S. (2023, April). *Navigating Telehealth Barriers to Deliver Effective ABA Services for Severe Problem Behavior: A Case Study, Latest Research, and Policy Insights*. Council of Autism Service Providers (CASP) Annual Conference, Tampa FL.
- **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**
 - *Nothing to report.*

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	<i>Scott Hall</i>
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-4797-1819
Nearest person month worked:	2
Contribution to Project:	Dr. Hall has supervised all study staff, coordinated meetings, and shared information with the collaborative members on the project. He has ensured that the research goals have been met in a timely manner with scientific integrity, that the work has been done within budgeted amounts and in compliance with the University and funding regulations.
Funding Support:	Department of Defense

Name:	<i>Joy Pollard</i>
Project Role:	Co-PI
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Dr. Pollard has participated in weekly team meetings and provided critical input to the study protocols. She has led the Stakeholder Board meetings and devised the telehealth protocol. She has participated in interview coding and discussed inter-rater discrepancies until consensus with the coding team.
Funding Support:	Department of Defense

Name:	<i>Leslie Quiroz</i>
Project Role:	Study Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5
Contribution to Project:	The study coordinator has screened, enrolled and conducted interviews with the caregiver, provider and payer stakeholders. She has also participated in all study meetings and facilitated the Stakeholder Board meetings.
Funding Support:	Department of Defense

- **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?

- *Nothing to Report.*

8. SPECIAL REPORTING REQUIREMENTS

- N/A

9. APPENDICES:

Appendix 1: Demographic characteristics of caregiver interview participants

Dyad #	Sex of child	Child age (years)	Mother age (years)	Duration of ABA therapy (years)	Number of ABA hours per week	ABA service location	Residential location
1	F	6	37	3	36	Clinic	Suburban
2	F	5	36	3	40	Home/clinic	Rural
3	M	7	38	1	12	Home	Rural
4	F	10	31	2	35	Home	Suburban
5	M	6	36	3	30	School	Suburban
6	M	4	28	1.5	30	Clinic	Urban
7	F	16	42	3	20	Home	Suburban
8	M	15	38	8	10	Home	Suburban
9	M	8	34	3	20	Home	Rural

Appendix 2: Representative quotes from caregiver interviews

Theme 1: Behavioral concerns

Social Communication. "She didn't seem like other kids her age. She didn't want to play with other kids. She had attachment issues. She didn't ever want to go with anyone she wasn't familiar with. Her communication skills are primarily echolalia, so her functional communication was poor".

Challenging behavior: "He was super aggressive towards the baby and he was actually super aggressive towards anyone, like any stranger. We would go to the park and he would attack like pretty much like hit anyone who came near him. We couldn't go to a story time he would freak out, he would, he was just extremely aggressive. He would hit, hit the baby to make him cry."

Anxiety/feeding problems: "if we tried to get her to eat a food that she did not want, she projectile vomited. it appeared to be like an anxiety reaction, more than anything, you could tell that her heart rate was going up, she was breathing faster, she was flushing and just the bringing of the food near her face. She would start gagging and retching and then it was all over."

Repetitive and stereotyped behaviors: "He was running back and forth and doing a certain thing, how can I put it, I mean, he would just do something repeatedly like he'd jump on the couch and he'd run around in a circle and then he'd jump back on the couch and run around in a circle, you know, just things like that."

Sleeping concerns: "Once she falls asleep, she wakes up a lot when she isn't able to go back to sleep. She doesn't like to be alone when she sleeps, it's always been a sleep problem. She will stay awake for 24 hours because she will just convince herself she's not tired. And the next day, she's just miserable and dragging but at night, she will not be tired because she will fully convince herself that she is just not sleepy and she doesn't need to sleep so she has multiple times stayed up for 24 hours plus because she just decided".

Theme 2: Barriers to accessing ABA services

Improving access to experienced ABA providers: "Almost none of them have experience working with teenagers - they all work with 3 year-olds, so it's really different to have a teenager, the current RBT is very new and I don't think she is trained well enough to provide an effective service, but they are in the process of training her."

Reducing delays in accessing ABA following a diagnostic evaluation: "There's two providers in our area that did clinic-based ABA and I reached out to both of them. Our early interventionist put us on their waiting list for one of the two as well and to this day I've never heard back from them, even though we're allegedly on their waiting list. So that's been years".

Minimizing challenging behavior related to travelling for therapies/services: "it would be very difficult to get her to the car, you know, whether it be a meltdown or, you know, she's running around and she's not eating and then morning sometimes, they used to be a lot more than they are now, just very stressful for Taylor, so by the time you get her in the car, you know, she is just frustrated and well so is mom or dad, you know, trying to get her in the car in the morning".

Minimizing the impact of treatment on the caregiver's job and their spouse's job. "You know it's stressful trying to manage because I'm a nurse, I'm in school, becoming a nurse practitioner and my husband, you know, he does shift work, he is a police officer, so it would just get hard managing all of our schedules and the traffic was just horrible you know".

Theme 3: Experience with ABA therapy

ABA provider turnover to decrease potential gaps in care: "their turnover was so poor, they treated their employees so poor. Turnover just kept going, going, going to the point where every time she was starting with a new therapist, she loses two weeks at a time, you have to pay for and do all that. So, and anytime I'd bring up those concerns they would get upset with me".

Disruptions that treatment can cause on daily family life: "It was a bit much, because this lady would be in our home, and nothing against her, I love her, she was amazing, but she was in our home from about 4:15 to about 7:15 every day. And so by the time she left, it was like, eat real quick, bathe and go to bed. He had no time to like rest and stuff, and neither did we, for that matter, you know, mom and dad, and I know it seems kind of selfish, but I had to take my life back. Because it was just too much for all of us."

Incorporating ABA more effectively in the schools: "I think it's a very underserved population. there's a gap, you know, you have a lot of services for early childhood education and, you know, elementary, but the services really start to lag and really be just nonexistent the older they get, by the time they hit middle school, which in our area is sixth grade um, it, it's really just up to the school districts and the lack of understanding, the lack of professional development that they get."

Improving communication between the caregiver and their ABA provider: "I remember there was several times that we would need to try to reach out and it would take days before she would reach back to us and then she would, she would give my husband attitude".

Challenges of coordinating schedules for treatment sessions. "it's definitely been a point of frustration. My husband did not work for three years and now he's only gone back to part time. We also have the help of my mother. It's a combination of that and her needing to be shuttled around and our son who's only 15 months younger, but he always has to go somewhere

else, because he does not have autism. So, doing the shuttling around because we all we would try and not have our son necessarily be in the car, all the time."

Theme 4: Cost of services/insurance

Reducing the financial impact related to insurance. "There's just the cost of paying for deductibles and making sure we have insurance, and we've had insurance issues where the insurance doesn't want to pay or whatever. It can be stressful because that's not in my control".

Learning more about the assessment and insurance authorization process. "They gave me all the insurance codes so that I can ask the place that I got him diagnosed, like how much it would be. And it was just really confusing. Like, why are you guys giving me all these codes? It's not helpful at all".

Identifying in-network providers and specialty areas. "So many in South Carolina don't have a coverage at all. The Medicaid kids, there's no providers in our area that accept Medicaid right now that I know of. And a waitlist for the Medicaid only kids is really, like I said, they do accept Medicare, but I've never heard back from them three years later".

Understanding your insurance coverage. "I mean, there were days I wouldn't sleep because I was researching everything, calling the insurance companies...which was very frustrating to me."

Theme 5: Benefits/drawbacks of telehealth service delivery models

Understanding which telehealth model is best for your child given your child's age or skill level. "I think that's one of the biggest challenges in telehealth at his age, you know, with him being seven years old, to sit down and do a conference with someone, or a session with someone for any longer than say 20, 30 minutes, that's excessive for his age."

Enabling your child to independently participate successfully via videoconference. "It's hard enough to get him to sit down and work with this teacher for 30 minutes a day, and that's very difficult. I can't see him sitting down for an hour. It would be something worth trying but I don't know that I have full faith in him being completely engaged either."

Comparing services via telehealth versus in-person. "I would have to say Telehealth is equal quality, if not more, just because of the ease of the simple phone call that can go through rather than, like I said, having to make the trip, I mean, there are still the boundaries and hours and kind of things that you need to consider and take into the whole scheme of things, but it's very nice to have somebody there that you can just kind of, call on when you need to."

Comparing telehealth supervision versus in-person supervision of ABA services. "It's also been great for the BCBA to be able to do supervision via telehealth because if they got sick or had a problem or anything happened, all of a sudden, you don't get services anymore. But if they're able to still do it via telehealth, you get more consistent services."

Learning more about the benefits of telehealth: "We didn't have to schedule a time for our therapist to come over. We didn't have to do anything like that, or make it some kind of long meeting that she would have to, you know, drive the 20 minutes, leave, then go back. We could just hop on a phone call or hop on a video chat and she was able to help us right away and kind of, help and give her some grounding techniques and calm her down and just to have another person that's not mom doing it."