A Pilot Feasibility Study of Parent Training for Young Children with Autism Spectrum Disorder in Rural Georgia Via Telehealth

Lawrence Scahill, MSN, PhD
Professor of Pediatrics
Emory University
lawrence.scahill@emory.edu

Karen Bearss, PhD
Assistant Professor of Pediatrics
Emory University
karen.bearss@emory.edu

Courtney Crooks, PhD
Senior Research Scientist
Georgia Tech Research Institute
courtney.crooks@gtri.gatech.edu

Felissa Goldstein, MD
Child Psychiatrist, Marcus Autism Center
Children's Healthcare of Atlanta
felissa.goldstein@choa.org

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Abstract

According to the 2012 report by the Centers for Disease Control, autism spectrum disorder (ASD) affects as many as 11.3 per 1000 children (CDC, 2012). As many as 50% of children with ASD between 3 to 8 years of age have disruptive behavior based on parent report. Parents describe frequent “meltdowns,” “sit-down strikes,” “noncompliance,” “aggressive outbursts,” “head banging,” “wrist biting” and other types of disruptive and challenging behavior in response to routine requests (Lecavalier, 2006). Over the past decade, we have developed and tested a 24-week structured parent training (PT) program for children with ASD and disruptive behaviors. Our PT is a time-limited intervention consisting of 13 sessions over six months. Trained therapists teach parents how to modify the child’s behavior – thus, parents are the change agents. We have demonstrated that trained therapists can reliably deliver the intervention, that PT is acceptable to parents and likely to reduce disruptive behavior in the children with ASD. It is not clear, however, that this program will be feasible for delivery via telehealth. In this application, we propose to extend our parent training program into rural Georgia via telehealth. Parent training will be delivered via telehealth from the Marcus Autism Center to parents of 10 children with ASD plus disruptive behavior in collaborating sites from the Georgia Partnership for Telehealth (GPT). To secure external funding, we have to show: that parent training can be reliably delivered via telehealth by trained therapists; that parents will accept telehealth as a method of delivering parent training; and that parents are satisfied with the parent training upon completion of the treatment. To measure success, we will monitor therapist fidelity to the manual, attrition, parental attendance at treatment sessions, compliance with homework assignments and overall satisfaction. We have assembled an outstanding team of investigators from Emory Department of Pediatrics, CHOA and Georgia Tech Research Institute to carry out this pilot study.
Specific Aims
The number of children identified with autism spectrum disorder (ASD) has increased over the past two decades (CDC, 2012). We now face the challenge of serving the growing number of identified children with ASD. Fortunately, the empirical foundation for behavioral and psychopharmacological intervention for children with ASD is also expanding. Among the more pressing challenges is how to disseminate the findings from randomized clinical trials to the clinic. The World Health Organization (2007) has noted the lack of specialists trained in assessment and empirically supported behavioral interventions for children with ASD. This shortage is more pronounced in rural areas. For children with ASD, this lack of access results in long drives and long delays in obtaining specialized behavioral services at Marcus Autism Center (Marcus). Marcus and Georgia Tech Research Institute (GTRI) have recently designed and implemented a telehealth system to provide autism screening, continuing care, treatment research and provider/caregiver training. This system offers a plausible solution to the problem of limited access for families in rural Georgia. Although the use of telehealth for specialty medical care is growing in Georgia, research and clinical application of behavioral interventions for children with ASD remain limited.

Over the past decade, we have developed and tested a 24-week structured parent training (PT) program for children with ASD and disruptive behavior. Disruptive behavior (tantrums, aggression, and active protest during ordinary tasks of everyday living) imposes an enormous strain on the family and results in reduced adaptive living skills in the child. Our body of work shows that parents embrace this intervention. Attrition is low, attendance is high, and parental engagement in PT is solid. Systematic application of PT reduces the child’s disruptive behavior and promotes adaptive skills (Bearss et al., 2013). Thus far, our PT program has been delivered individually to parents by trained therapists in five expert US centers (Randomized Trial of Parent Training for Young Children with Autism; R01MH081148; Scahill, PI). It is now time to disseminate this treatment beyond the confines of these specialized centers. The purpose of this pilot project is to demonstrate the feasibility of delivering PT to families in rural Georgia via telehealth. We propose a 14-month project in order to deliver the 24-week intervention to 10 families.

We have shown that trained therapists can reliably deliver PT. It is acceptable to parents and predictably reduces disruptive behavior in the children with ASD. However, it is not clear that PT will be feasible for delivery via telehealth. Thus, the aim of this pilot project is to evaluate whether our PT program can be successfully delivered to parents of children with ASD and disruptive behavior living in rural Georgia using telehealth. We will evaluate whether therapists can deliver the treatment reliably, whether parents will find this novel delivery of PT acceptable and if it achieves a high level of parent satisfaction. We will also gather preliminary evidence of benefit for participating children. Answers to these questions are necessary prerequisites for proposing a larger more definitive study.

Aim # 1. To demonstrate the feasibility of Parent Training (PT) delivered individually via telehealth to parents of 10 children with ASD and disruptive behavior (ages of 3 and 8 years).
We define feasibility: evidence that PT can be reliably delivered using telehealth and that PT is acceptable to parents. Feasibility also requires demonstrating successful collection of study outcome measures. Feasibility benchmarks:
a) Therapists will show > 80% fidelity to the PT manual for the 10 cases (review of recorded sessions using a checklist for each session)
b) Fewer than 20% of families will drop out of treatment and parents will attend ≥ 70% of core PT sessions (sessions attended + expected X 100).
c) Parents will show > 80% therapist-rated compliance with PT homework assignments.
d) Research team will collect ≥ 90% of essential outcome measures (actual ratings + expected X 100).

Aim # 2. To evaluate the preliminary efficacy of PT for reducing disruptive behavior and improving adaptive functioning in 10 children with ASD.
The primary outcome measures include the parent-rated Irritability subscale of the Aberrant Checklist and the total score on the parent-rated Home Situations Questionnaire. Other measures of interest include clinician-rated Clinical Global Impression for Improvement, the Vineland Adaptive Behavior scales and the Caregiver’s Strain Questionnaire.
Behavior Checklist
nearly completed
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behavioral problems

The Research Units on Pediatric Psychopharmacology (RUPP) Autism Network developed for a more careful evaluation of the efficacy of PT when delivered vi
families in rural Georgia.

state of the art telehealth equipment
ASD. The Georgia Partnership for Telehealth
the community.  Families in rural
implementation of the intervention
The
and disruptive behavior. PT provides tools t
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Our
behavior and promote adaptive skill acquisition
consistent daily
practitioners)
PT is limited
consisting of 13 sessions over six months. Trained therapists teach parents how to modify the child’s behavior – thus, parents are the change agents. PT is practical. It targets daily activities such as getting dressed, getting ready for bed, getting on the school bus or managing trips to the grocery store that often become daily struggles for families of children with ASD. Children with ASD with deficits in functional communication often fail to use words to indicate wants and needs. Acting out becomes a way of obtaining objects of interest (food) or escaping from routine demands (getting dressed for school). Parents inadvertently reinforce these behaviors by “giving in” to the child’s demand. For example, a mother regularly facing active and prolonged protest to get a child to get dressed may understandably complete the task for the child. This pattern of noncompliance interferes with the regular performance of acquired skills and the acquisition of new skills (Scahill et al., 2012). Over time, parents become profoundly uncertain on how to manage noncompliant and disruptive behavior. PT provides tools to reduce noncompliance and promote adaptive functioning.

The PT manual includes validated techniques into a standardized format that promotes consistent implementation of the intervention in research studies. We now seek to disseminate this intervention in the community. Families in rural Georgia have limited access to specialized treatment for children with ASD. The Georgia Partnership for Telehealth (GPT) is expanding into every corner of the state (http://www.gatelehealth.org/index.php). Marcus (part of CHO) is connected with the GPT and we have state of the art telehealth equipment that is being used on a regular basis by Dr. Felissa Goldstein (child psychiatrist on staff at CHO). In short, we are poised to conduct a pilot trial of PT via telehealth with 10 families in rural Georgia. We intend to use the feasibility findings as data to support a larger proposal for a more careful evaluation of the efficacy of PT when delivered via telehealth.

Efficacy of PT for children with ASD and disruptive behavior using a ‘face-to-face’ service delivery model: The Research Units on Pediatric Psychopharmacology (RUPP) Autism Network developed the structured 24-week PT program (Johnson et al., 2007) and completed a successful multi-site feasibility trial (RUPP Autism Network, 2007). This was followed by a large scale randomized trial of risperidone only versus risperidone plus parent training for school age children with ASD accompanied by serious behavioral problems (Aman et al, 2009; Scahill et al., 2012). In this study PT was an adjunct to medication. We then made further revision of the manual for younger children with ASD and disruptive behaviors as a stand-alone treatment and conducted a trial in 16 children between the ages of 3 and 7 years (Bearss et al., 2013). With funding from the National Institute of Mental Health (NIMH), we have nearly completed a multi-site trial of PT in 180 preschool-age children with ASD plus disruptive behavior.

For the first three trials, primary outcomes of interest included changes on the parent-rated Aberrant Behavior Checklist – Irritability subscale (ABC-I) and Home Situations Questionnaire (HSQ). The ABC-I
have a diagnosis of ASD using state of the art assessments, have a score
enroll 10 eligible and willing subjects.
will be invited to come to Marcus for the baseline assessment. We expect to evaluate 15 children to
the GPT clinical sites. Families of potentially eligible children will be scr
Georgia. In addition, though Dr. Goldstein’s contacts across the state, we expect to receive referrals from
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( one to two subjects per month). The intervention is six months in duration and we propose a three
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Approach
Telehealth (GPT)
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is Project
Director of the effort to design and implement the upgraded telehealth system at Marcus. In partnership
with GTRI, Marcus now has a state of the art telehealth suite. The system includes large, high definition
monitors, specialized lighting and enhanced audio. These enhancements are ready for application of PT
in young children with ASD and disruptive behavior. Thus, although the application of telehealth for
research in children with ASD is new, this project brings together expertise in clinical trials (Dr.
Scahill), parent training (Dr. Bearss) and telehealth (Drs. Goldstein and Crooks). The novel application of
telehealth for the delivery of PT in rural Georgia is also made possible by the Georgia Partnership for
Telehealth (GPT). GPT is a nonprofit corporation connected with 350 locations involving over 200
specialists and healthcare providers. The professed mission of GPT is to provide general and specialty
health care services to underserved rural areas in Georgia. Our proposed pilot study will be an important
step toward the dissemination of PT via telehealth.

Innovation
Telehealth uses advanced communication technologies to deliver general medical and specialty services
by experts in real-time over a geographical distance. It is cost effective. It reduces travel time, missed
visits related to travel burdens, and increases access to specialized treatments. The increase in access
may also save money in the long run by decreasing disability associated with unmet needs. Drs.
Goldstein and Crooks have experience in using telehealth. Dr. Goldstein has been using telehealth for
assessment and follow up of children with ASD for several years. Dr. Crooks, from GTRI, is Project
Director of the effort to design and implement the upgraded telehealth system at Marcus. In partnership
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step toward the dissemination of PT via telehealth.

Approach
Ten children with ASD and disruptive behaviors will be enrolled over the first six months of the project
(one to two subjects per month). The intervention is six months in duration and we propose a three-
month, post-treatment follow up. Thus, each child will be monitored for a total of nine months. Children
will be recruited through the Marcus Autism Center, which receives referrals from all over the state of
Georgia. In addition, though Dr. Goldstein’s contacts across the state, we expect to receive referrals from
the GPT clinical sites. Families of potentially eligible children will be screened by phone. Then families
will be invited to come to Marcus for the baseline assessment. We expect to evaluate 15 children to
enroll 10 eligible and willing subjects.

Table 1 displays the significant improvement from Baseline to Week 24 on the ABC-I and HSQ. Across
the three trials, attrition was low (13-18%) and parents attended 84-93% of the therapy sessions. In
addition, parent adherence to session materials and homework assignments was solid ranging from 80-
89%. These results provide strong evidence that parents found PT acceptable and they were engaged in
the treatment. Therapist adherence to the treatment was also high, ranging from 93-95%. The results
parental acceptance, parental engagement, therapist fidelity (and preliminary efficacy) of the proposed
pilot study of PT via telehealth can be compared to the results of these prior studies.

<table>
<thead>
<tr>
<th></th>
<th>Pilot # 1 (N=17)*</th>
<th>Drug + PT (N=75) **</th>
<th>Pilot #2 (N=16) **</th>
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<tbody>
<tr>
<td></td>
<td>BL</td>
<td>Week 24</td>
<td>BL</td>
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<tr>
<td>ABC-I</td>
<td>24.3 (9.3)</td>
<td>16.1 (9.5)</td>
<td>29.3 (7.0)</td>
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<td></td>
<td>16.0 (9.2)</td>
<td>3.0 (1.1)</td>
<td>1.2 (1.4)</td>
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<tr>
<td>HSQ</td>
<td>3.6 (1.1)</td>
<td>2.2 (1.5)</td>
<td>4.3 (1.7)</td>
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<td></td>
<td>1.6 (1.5)</td>
<td>1.4 (1.2)</td>
<td>1.4 (1.2)</td>
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Table 1. Prior studies of PT in Children with ASD and Disruptive Behavior

Table 2 presents the schedule of measures. Eligible subjects will be between the ages of 3-8 years,
have a diagnosis of ASD using state of the art assessments, have a score > 15 on the parent-rated
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Aberrant Behavior Checklist Irritability subscale (moderate level of disruptive behavior), Receptive Language age equivalent > 18 months. In addition, subjects will be medication free, but if on medication, the medication dose must be stable for at least four weeks with no planned changes for 6 months. Anticonvulsants will be allowed if the dosage has been stable for 4 weeks and the patient is seizure free for at least 6 months. The Baseline visit will involve diagnostic and cognitive testing of the child, collecting standardized paper-and-pencil ratings from parents, and a parent interview conducted by the study Independent Evaluator (IE). We expect the baseline assessment to take 4 hours.

Table 2. Study Measures

<table>
<thead>
<tr>
<th>Subject Characterization</th>
<th>Baseline</th>
<th>8</th>
<th>12</th>
<th>16</th>
<th>24</th>
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</thead>
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<td>Demographic Form</td>
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<tr>
<td>Autism Diagnostic Observation Schedule</td>
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<tr>
<td>Cognitive Test (Mullen or Stanford-Binet V)</td>
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<tr>
<td>Services Inventory Form</td>
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<td>Social Communication Questionnaire</td>
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<tr>
<td>Clinical Global Impression-Severity</td>
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<tr>
<th>Outcome Measures</th>
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<tbody>
<tr>
<td>Aberrant Behavior Checklist</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Home Situations Questionnaire</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Vineland</td>
<td>X</td>
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<tr>
<td>Clinical Global Impression for Improvement</td>
<td>X</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Parent Target Problem</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Caregiver Strain Questionnaire</td>
<td>X</td>
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<tr>
<td>Parent Satisfaction Rating</td>
<td>X</td>
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<th>Therapist Measures</th>
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<tbody>
<tr>
<td>Treatment Fidelity Checklist</td>
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<tr>
<td>Parent Treatment Adherence</td>
<td>After each therapy session</td>
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Follow-up Assessments: Follow-up assessments will be conducted at Weeks 8, 12, 16, and 24. All assessments will include completion of parent-report measures as well as ratings by a clinician not involved in PT (independent evaluator). The routine follow-up visits, which will take about one hour, will be done via mail (parent ratings) and telehealth (clinician ratings).

The PT program includes 11 core sessions and up to 2 optional sessions over the course of 16 weeks, with each session taking 75 to 90 minutes to complete. The core sessions include the basics of behavior modification and skill acquisition. The optional sessions may include review of specific sessions or sessions focused on an individual problem (e.g., toileting or sleep). The program allows 16 weeks to complete the 11-13 sessions to accommodate schedule changes and cancellations. Three phone booster sessions then occur every 2 weeks until Week 24 for generalization and maintenance of skills. The PT manual includes detailed therapist scripts and instructions to promote treatment fidelity. The treatment sessions employ direct instruction, role-playing and reviewing video vignettes to illustrate points made in therapy sessions. Parents are also given homework between sessions that focus on applying the new techniques to a specific behavior.

Measuring feasibility of PT via telehealth for children with ASD and disruptive behavior.

Therapist Fidelity. The therapist will rate herself on 5 to 7 items after each session (0 = goal was not achieved; 1 = goal was partially achieved; 2 = goal was fully achieved). The score for each session is then expressed as a percentage (actual score across all items divided by the total possible score X 100). Using results from prior RUPP studies as a guide, we propose a minimum benchmark of ≥ 80% for therapist reliability. All therapy sessions will be recorded on video from Marcus and the host telehealth site using technology from GTRI. As a check on the therapist rating, we will independently review therapist reliability in the 10% random sample of recorded sessions. The video recordings may also be useful for exploratory analysis that could inform future studies.
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Session Attendance and Attrition. In prior RUPP studies, we observed an 84 to 93% attendance rate of PT sessions and a drop out rate of 13 to 17%. We propose a minimum benchmark of > 85% for parental attendance to treatment sessions and an attrition rate of ≤ 20%.

Parental Engagement After each session, the therapist will complete a checklist designed to measure parental involvement and understanding of the session materials and parental completion of homework from the previous session. Based on previous RUPP studies, we propose a benchmark of > 80% for parental adherence to PT assignments and engagement across sessions.

Parent Satisfaction will be assessed with a 16-item parent satisfaction rating scale administered at Week 24. In our prior studies, the mean parent satisfaction score was 47.6 (SD 4.0) on a 52-point scale (higher scores reflect greater satisfaction). We aim to obtain a mean score ≥ 45.

Outcome Measurement. Assessment visits in our prior trials were conducted in the clinic, often in conjunction with treatment visits. In preparation of a larger-scale efficacy trial, we need to establish that outcome measures can be collected in the context of telehealth delivery. Our goal is to keep missing data for each outcome measure below 10%.

Exploratory Analyses. This pilot trial is not about efficacy. We will conduct exploratory analyses on outcome measures that we have used in prior trials. These include: Irritability subscale of the Aberrant Behavior Checklist (ABC-I), the Home Situations Questionnaire (HSQ) and the Caregiver Strain Questionnaire (CSQ). Based on our model that noncompliant behavior contributes to impaired adaptive functioning in children with ASD, another outcome of interest will be the Vineland Adaptive Behavior Scales. The ABC-I and HSQ will be evaluated with repeated measures mixed model. The CSQ and the Vineland will be evaluated with ANCOVA with the baseline score in the model. Finally, we will evaluate whether gains achieved during the 24-week trial endure for 3 months post-treatment with ANCOVA models on the ABC-I and HSQ.

Data management and statistics will be done by Mr. Scott Gillespie and Dr. Courtney McCracken who are part of the statistics core at Marcus.

Investigators
Attached to this application are biosketches of the PI (Dr. Scaghill) and co-investigators (Drs. Bearss, Goldstein and Crooks). A strength of this proposal is the unique and complementary skills of this research team. Dr. Scaghill has over 20 years of experience in designing and conducting clinical trials in children with neurodevelopmental disabilities. For the last 15 years, he has been a principal investigator in the Research Units on Pediatric Psychopharmacology Autism Network (2002). The RUPP Autism Network has completed a series of pivotal studies in the field. He is also the PI of an NIMH-funded, multi-site trial of PT versus parent education in young children with ASD plus disruptive behavior. Dr. Bearss is a psychologist with expertise in parent training. She was the primary author of the manual being used in the nearly completed multisite of parent training. She will train and supervise the post-doctoral fellow who will provide the parent training via telehealth. Dr. Goldstein is a CHOA child psychiatrist with extensive experience in providing clinical services via telehealth in Georgia. She has established contacts throughout the state. Dr. Crooks is a psychologist with additional training and experience in engineering and video technology. She was central to the collaborative development of the GTRI-Marcus collaboration that established the telehealth studio at Marcus. We are also fortunate to have the statistical support from Mr. Scott Gillespie and Dr. Courtney McCracken from the Marcus statistical core.

BUDGET
Post-doctoral Fellow – Elizabeth Mitchell, PhD. 39% effort and 39% support. Dr. Mitchell is currently a first year post-doctoral fellow at Marcus. We have arranged for her to begin training on the PT intervention over the next few months – at which point she would be ready to implement study cases.

Subject Payments: $ 4,900 is needed for participants and their families.
- Subjects and families will be offered $50 for the screening visit (13 screened; 10 entered = 13 * $50 = $650)
- $25 for 4 follow-up assessment visits (10 subjects * 4 assess * $25 = $1000).
- $25 for up to 13 therapy sessions (10 subjects * 13 sessions * $25 = $3250).
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References


