

Examining A Stepped-Care Telehealth Program for Parents of Young Children With Autism: A Proof of Concept Trial

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Abstract

Background Intervention during the first years of life for children with autism spectrum disorder (ASD) may have the strongest impact on brain development, behavior and long-term functioning. Yet, barriers such as a shortage of trained professionals contribute to significant delays in service. The goal of this proof-of-concept study was to explore strategies that support timely and equitable deployment of ASD-specific interventions.

Methods We conducted a 15-week, randomized control trial (RCT) comparing a stepped-care model (i.e. parents first used an interactive website, and then received parent coaching if warranted) of Online Reciprocal Imitation Training (RIT; a naturalistic developmental behavioral intervention) versus a waitlist control condition (WLC). To be eligible, children had to be between 18 to 60 months, meet the cutoff for ASD on the Autism Diagnostic Observation Schedule-2 Edition and demonstrate significant social imitation deficits. Primary outcome measures included child imitation skills (Unstructured Imitation Assessment (UIA)), parental self-efficacy (Early Intervention Parenting Self-Efficacy Scale (EIPSES)), and parent fidelity (RIT Parent Fidelity Form (RIT-PFF)) to the intervention. Secondary outcome measures included child social communication (Social Communication Checklist (SCC)) and family quality of life (Beach Center Family Quality of Life Scale (FQOL)).

Results Twenty participants were randomized in a 1:1 fashion, after participant drop out, eight were in the WLC and seven were in Online RIT. Among the primary outcomes, there were significant group differences and improvements in parent fidelity ($p = .000$), self-efficacy ($p = .029$), and ratings of child social communication ($p = .048$) in Online RIT relative to wait-list controls. There was no significant difference of improvement in imitation ability ($p = .05$) or family quality of life ($p = .220$).

Limitations There are several limitations with this study, including the small sample size, lack of enactment data, and a lack of website engagement data. The WLC design limits the strength of the conclusions that can be drawn.

Conclusions Overall, the novel use of stepped-care telehealth shows strong acceptability and holds promise as an innovative delivery model.

Trial Registration Trial Registration: ClinicalTrials.gov, NCT04467073. Registered 10 July 2020- Retrospectively registered, <https://clinicaltrials.gov/ct2/show/NCT04467073>

Background

There are clear benefits to early autism spectrum disorder (ASD)-specific interventions for young children with and at-risk for ASD (1). Yet, limited availability of services results in many children “missing out” on intervention during the key developmental period proposed to have the most powerful effect on gene expression, brain development and behavior (2). The discrepancy between service need and access is compounded for those in underserved communities where children receive even fewer interventions and at later ages (3). Commonly cited barriers to care include transportation issues, limited funding, and a shortage of well-trained professionals, all of which contribute to significant waitlists and delays in care (4). Research examining strategies to directly address these barriers and support deployment of ASD-specific interventions in a timely, equitable and efficient manner is a top priority (5).

Naturalistic Developmental Behavioral Interventions (NDBIs)

There is growing evidence for Naturalistic Developmental Behavioral Interventions (NDBIs), a category of interventions that merge applied behavioral and developmental sciences, for improving social communication and developmental outcomes in young children with and at-risk for ASD (6). While each NDBI has specific features, they are characterized by commonalities in terms of the nature of learning targets (e.g., focus on building a social learning infrastructure), learning contexts (e.g., teaching within naturalistic contexts), and development-enhancing strategies. NDBIs share evidence-based strategies such as use of a three-part contingency, child-initiated teaching episodes, environmental arrangement, and natural reinforcement (see 7 for a full list of shared strategies). Best practice indicates that delivery of NDBIs should be initiated as early as possible, include a parent component, and concurrently address underlying core deficits and teach new skills (6, 7).

Comprehensive NDBIs, such as the Early Start Denver Model (ESDM; (8)) target a number of broad functional outcomes and therefore are often intensive in terms of resources, time, and duration, and rely on highly trained interdisciplinary specialists (9). The importance of comprehensive services should not be understated; however, the complex nature of these programs may complicate access, adoption and implementation especially in community settings (10). In particular, families who have access to traditional comprehensive interventions vastly underutilize the hours they are allotted (11). Additionally, recent estimates indicate an average time-lag of roughly 3 years between diagnosis and receipt of early intensive behavioral intervention in the community (12). Further, the younger a child at diagnosis, the greater the time-lag to service access, suggesting a significant gap in care during a period when the child and family may be particularly vulnerable (12).

Given the current services landscape, it is critical to consider additional models such as focused NDBIs, which may be particularly well suited to serve as a “bridge” or supplement to more comprehensive approaches. Focused interventions teach a specific skill or set of skills, are often less complex and intensive, and hold promise for more efficient dissemination and adoption across formats (e.g., parent mediated intervention) and settings (e.g., early childhood classrooms, home-based IDEA Part C services). Research suggests a number of focused NDBIs, such as Reciprocal Imitation Training (RIT) and Joint Attention Symbolic Play Engagement and Regulation (JASPER), can improve specific social communication skills at a relatively low intensity and when implemented by caregivers and other key members of a child’s community (13-16). Taken together, focused NDBIs are particularly well-suited for use when examining innovative delivery models to provide care to families without or with limited access to evidence-based services.

Telehealth

Telehealth, or the ability to provide long-distance health care and education, has been one of the most rapidly growing fields of research and clinical care in the last decade. Eighty one percent of U.S. households now have a broadband internet subscription (17). The numbers are even greater for families with children <18 at home with 97% reporting household computer access and 90% reporting broadband internet subscriptions. Given the intuitive appeal of telehealth, this delivery model has already been adopted in community settings. Prior to the COVID-19 pandemic, two thirds of U.S. hospitals employ some kind of telehealth technology, one third of states have enacted telehealth parity laws, and nearly all state Medicaid programs cover at least some form of telehealth (18). As of 2012, 13 states had incorporated telehealth into the state Early Intervention (IDEA Part C) service model (19). This number has only grown over the last decade, and most recently during the global COVID-19 pandemic, with several states launching initiatives to support statewide implementation of telehealth-based Early

Intervention services (20). The scientific data and stakeholder excitement around telehealth suggests that it is poised to serve as a viable alternative or supplement to traditional service delivery models with potential to deliver care in an effective, acceptable, and cost-efficient manner (21). However, additional research is required to determine optimal program structure, telehealth procedures and dissemination strategies to ensure successful implementation of research-based telehealth programs in the real world.

Telehealth can be used to deliver intervention in a variety of formats. For example, there is a growing emphasis on the use of self-directed applications (e.g., smart phone apps) and websites to deliver evidence-based intervention such as cognitive behavioral therapy (CBT) for common psychiatric conditions such as depression (22, 23). Similarly, preliminary telehealth early intervention research in ASD explored self-directed websites to deliver parent training in NDBIs (24, 25). While the use of self-directed programs is appealing for greater flexibility of user engagement, reduced costs, and subsequent ease of larger scale dissemination, limitations to this approach must be considered. For example, data from mixed methods studies indicate that parents in self-directed programs are more likely to report barriers to participation (such as time), less likely engage with and complete in all aspects of the website, and less likely to report gains in child skills (26, 27). These findings suggest attenuated effects of self-directed telehealth programs for many telehealth users; however, the specific predictors of self-directed program engagement and outcome remain largely unknown.

Research has also examined the use of videoconferencing to deliver instruction and parent coaching to support skill acquisition in caregivers of children with ASD (28-31). This approach is often referred to as “real-time” or synchronous telehealth. For example, Bearss²⁸ and colleagues used synchronous eHealth to deliver the RUBI Autism Network Parent Training (PT) program. The feasibility trial suggested high rates of therapist fidelity, high rates of program engagement and completion, and reported improvements for the majority of the child participants. Despite the promise of these data, remote parent coaching alone still does not address the significant barrier of a shortage of trained professionals in community settings.

Importantly, self-directed and remote parent coaching telehealth approaches can be integrated for more effective service delivery. For example, a parent could access digital tools (in the form of a website or game) to learn the intervention content at their own time at pace, and then connect remotely with a professional to get feedback on their use of the strategies and help with problem solving and planning. Ingersoll²⁶ and colleagues compared use of an interactive website alone to the website plus videoconferencing with a therapist. Results indicated that both groups showed gains from pre- to post-intervention across parent and child outcomes. However, parents in the therapist-assisted condition improved more in their intervention fidelity and increased positive perceptions of their child, and the children in that condition showed greater gains in social skills. Although there is limited understanding of the specific variables predicting response to treatment, these data support the notion that tailoring of both digital tools (e.g., interactive website) and coaching approaches should be explored to enhance learning and application of skill from such hybrid telehealth programs (32). Equally as important is the close consideration of personalized telehealth models to maximize reach and efficiency of service delivery.

Adaptive Interventions

Given this modest evidence for the “one size fits all” telehealth approach, an examination of individualized models for promising NDBIs is warranted. Adaptive interventions allow for variation in intervention intensity as a function of individual or environmental characteristics and treatment response (33). Adaptive interventions may be especially fitting when there are: high levels of heterogeneity in treatment response and a need to consider a

cost-benefit trade-off between intervention intensity and available resources (34). Given the current state of ASD research and practice, there is a strong rationale for exploration of adaptive telehealth NDBIs.

Stepped-care is a model of adaptive intervention which offers less intensive intervention as a first-line treatment, and more intensive care only when clinically indicated. Decisions about who receives “stepped up” care are data-driven in that they are informed by closely monitoring patient outcomes using what are referred to as tailoring variables to determine if and when additional care is indicated. Stepped-care models have been designed for the delivery of interventions for eating disorders, substance abuse, anxiety, depression and childhood trauma, and data indicate it is an effective, acceptable and cost-efficient model, particularly for brief interventions (35). Investigators have suggested that stepped-care may be an especially promising delivery model for targeted early interventions for ASD (2) but research has not yet examined a stepped-care parent training intervention for ASD.

Current Study

This proof-of-concept study addresses the gap in the current literature by examining a stepped-care version of a telehealth NDBI, Online RIT. Online RIT is an interactive website introducing Reciprocal Imitation Training (RIT), an NDBI focused on enhancing social imitation (27). RIT uses a naturalistic behavioral approach to teach object and gesture imitation to young children with ASD within a play-based context. The efficacy of RIT has been demonstrated through a small randomized control trial (13, 14), several single-subject design studies (36, 37), as well as in independent replications (38-40). Prior research also suggests that parents can be taught to effectively use RIT with their children in person (15), and two single-subject design studies detail the development and feasibility testing of Online RIT plus therapist assistance (25, 27). In Study 1, parents used the website and received in-vivo coaching; children showed corresponding improvements in imitation (25). In Study 2, parents used the website with remote coaching; parents improved in RIT fidelity across study phases, and concurrent improvements in child imitation were observed. All families received remote coaching, but 2/5 achieved the fidelity threshold after the website alone (27). These preliminary data suggest Online RIT may serve as an ideal platform for examining the potential of individualized telehealth delivery formats, such as stepped-care. Therefore, the goal of this study was to compare a stepped-care format of Online RIT to a waitlist control condition to determine initial feasibility and effectiveness of this innovative intervention and service delivery model.

Methods

Participants

Twenty families of a child with ASD were recruited for the current study via clinician referrals, community partner referrals and recruitment postings on social media. To be eligible for screening, children had to be between 18 and 60 months, have a diagnosis of ASD or significant concerns of ASD, and parent reported imitation deficits. Participants were asked to keep behavioral, educational and pharmacological intervention stable for the duration of the trial. Children of parents who were non-English speaking or who were actively participating in other parent training programs were excluded. Families were not charged for study assessments or intervention and they received \$40 in amazon.com gift cards for participation.

Study design

The Institutional Review Board (IRB) at Rush University Medical Center (RUMC) (IRB 15100203) approved this 15-week randomized controlled trial (RCT) comparing a stepped-care model of Online RIT to a waitlist control condition (WLC). Participants signed informed consent at the in-person screening/baseline visit, before any data collection began. Participants completed baseline and post-intervention behavioral assessments at RUMC, while the rest of the data collection and study participation occurred remotely. Questionnaires were collected electronically via Qualtrics, and home-based parent-child interactions recorded from videoconferences using Vidyo (see below). Participants were randomly assigned to one of two conditions using a computerized randomization program.

Eligibility and Sample Characteristics

To be eligible for participation in the study, children had to be between 18 and 60 months, meet the cutoff for ASD on the Autism Diagnostic Observation Schedule-2 Edition (41), and demonstrate significant social imitation deficits (<50%) on the Unstructured Imitation Assessment (UIA, (14)). Children were also administered the Mullen Scales of Early Learning (Mullen, (42)) to provide an estimate of nonverbal and expressive language levels. See the study consort diagram (Figure 1) and Table 1 for participant demographic information.

Measures

Participant characterization

Demographics. A demographics form used in prior trials (26) was completed by parents and included information about the child, participating parent, and family structure.

Mullen Scales of Early Learning (Mullen; (42)). The MSEL was administered to provide an index of the child's developmental level at intake. Specifically, Visual Reception age equivalents were used to estimate nonverbal mental age and Expressive Language age equivalents were used to estimate child expressive language age.

Computer-Email-Web (CEW) Fluency Scale (43). The CEW Fluency Scale is a self-report measure designed to assess an individual's fluency with the computer, email and the web. For the purposes of the current study, 5-items were used to characterize participant familiarity and comfort with computer and internet technology (see Table 1).

Services Questionnaire. The *Services Questionnaire* asks parents to indicate the intervention services a child received in the past and the services the child is current receiving, including the number of weekly hours received for each service. Total weekly hours of services were summed for a total score for each participant.

Parent Outcome Measures

RIT Parent Fidelity Form (RIT-PFF; (27)). Trained observers scored the parent-child interactions for parent fidelity of the RIT intervention techniques using the RIT fidelity form (see (27) for behavioral definitions). Parent behavior was rated from 5 (high) to 1 (low) across six domains: Contingent Imitation, Linguistic Mapping, Modeling, Prompting, Reinforcement and Pacing. The last four domains were averaged to derive a Prompting Sequence score. Ratings on Contingent Imitation, Linguistic Mapping and Prompting Sequence were averaged for an Overall Fidelity Score. Raters were blind to participant condition and time point. Ten percent were double coded to ensure interrater reliability of 80% or higher.

Early Intervention Parenting Self-Efficacy Scale (EIPSES; (44)). The EIPSES is a 20-item parent questionnaire designed to measure parenting efficacy within the context of early intervention (e.g., “when my child shows improvement, it is because I am able to make a difference in my child’s development”). Participants rate the extent to which they agree with statements from *Strongly Disagree* (1) to *Strongly Agree* (7). The EIPSES provides two index scores (Parent Outcomes Expectations and Parent Competence) and an overall score. For the purposes of the current study, the EIPSES overall score was used for data analysis.

Beach Center Family Quality of Life Scale (FQOL Scale; (45)). The FQOL Scale is a 25-item self-report measure designed to assess family interaction, parenting, emotional well-being, physical/maternal well-being, and disability-related supports. Participants rate the extent to which they are satisfied with these various aspects of family interaction and experience from *Very Dissatisfied* (1) to *Very Satisfied* (5). An overall Total Score was calculated by averaging all items.

Child Outcome Measures

Social Communication Checklist (SCC; (46)). The SCC is a 47-item checklist completed by parents to indicate if a child uses a specific social communication skill *Rarely/Not Yet* (1), *Sometimes, but not consistently* (2), or *Usually, at least 75% of the time* (3). Scores in the areas of social engagement, language/communication and imitation/play can be derived and then summed for an SCC Total Score.

Unstructured Imitation Assessment (UIA; (14)). The UIA was used to measure child social imitation. It is a standardized assessment that evaluates spontaneous imitation of actions with objects and gestures during play. The examiner provides 20 different imitation bids (10 object, 10 gesture). Each bid is repeated three times. Child responses are rated as “0” none, “1” partial, or “2” full. The highest score for each imitation bid is summed for an overall UIA score. The UIA was coded by raters blind to participant condition and time point for the current study. Thirty percent were double coded to ensure interrater reliability of 80% or higher.

Acceptability

Scale of Treatment Perceptions (STP; (47)). The STP is a measure of treatment acceptability targeting skill building interventions, particularly for children with ASD. The STP was adapted to include language specifically referencing RIT, resulting in a 24 item questionnaire which provides an index of the perceived effectiveness of RIT, the fit between RIT and the family, and the safety of RIT. Participants rate the extent to which they agree with the statements from *Strongly Disagree* (1) to *Strongly Agree* (7).

Online RIT Attributes. This scale was adapted from Moore and Benbasat’s⁽⁴⁸⁾ instrument to measure the perceptions of adopting an information technology innovation. This brief adapted version (18 items) has been used in intervention studies similar to the current work (49). Participants indicate level of agreement from *Strongly Disagree* (1) to *Strongly Agree* (7). This adapted scale provides domain scores mapping onto four critical characteristics of innovations (50): observability, complexity (with higher scores reflecting less complexity), acceptability, relative advantage.

Intervention & Service Delivery Platforms

Online RIT is an interactive website developed to deliver instruction in RIT to parents of young children with or at-risk for ASD. Program development was guided by the technology acceptance model, media richness theory (i.e.

which technologies best reduce uncertainty and equivocality), and principles of instructional design (51-53). A collaborative and iterative development process with pilot participants was employed to ensure acceptability and usability. Online RIT is hosted on a unique URL owned and managed by RUMC, requires a unique username and password to log in, and is consistent with “best practices” in terms of safeguards to ensure website security. The program is mobile device and computer compatible.

Online RIT presents RIT techniques in four sequential learning modules: (1) *Setting Up For Success* (e.g., select activities, antecedent controls, scheduling practice time, ensuring a support system); (2) *Imitating your Child* (contingent imitation, imitating the child’s vocalizations, gestures, body movements and play with toys); (3) *Describing Play* (linguistic mapping, using simple and descriptive language at or slightly above the child’s linguistic level); (4) *Teaching Object Imitation* (using modeling, prompting, reinforcement to teach a target skill, and pacing the interaction). Each learning module includes an instructional video, quiz, interactive exercises, and at-home planning and reflection. The website also includes a video library, Frequently Asked Questions, downloadable visual aids, links to relevant external resources, and a customizable “dashboard” that allows users to track their individualized goals and the amount of time they have spent working on their goals (e.g., practice log).

Parent coaching sessions were held remotely using Vidyo, which provides secure bidirectional audio and video conferencing capability along with advanced capabilities such as content/screen sharing, video streaming, far end camera control, encryption, DTMF controls and more. Vidyo meets HIPAA privacy standards and has built-in security management (e.g., SSL certificates, private key management, and HTTPS all FIPS 140-2 compliance). Participants in the current study downloaded an app to their smartphone, tablet or computer to allow for seamless videoconferencing.

Study procedures.

Screening/Baseline. Participants attended one-to-two days of testing at RUMC to complete participant characterization assessments and outcomes. Immediately after screening/baseline visits, participants engaged in a home-based parent-child interaction which was later coded for parent fidelity.

Randomization. A computerized randomization program was used to determine treatment condition assignment following screening/baseline assessments. Participants were enrolled on a 1-1 schedule to Online RIT or wait-list control.

Study Conditions

Stepped-Care Online RIT. Parents randomized to Online RIT completed the four modules over a period of 5 weeks (~1 per week, 1 week to practice). Prior research on parent training in RIT and related NDBIs suggests improvements in post-treatment parent fidelity and parent empowerment/self-efficacy (54, 55). As such, these two variables were selected as tailoring variables for this stepped-care model. Fidelity (RIT-PFF) and self-efficacy (EIPSES) at 5 weeks were used to determine which participants were in need of a “step up” in care, in the form of remote parent coaching.

Parents who demonstrated $\geq 80\%$ on the RIT-PFF, and who reported gains on the EIPSES continued to have access to Online RIT and practiced on their own for the next 5 weeks, but did not receive any remote coaching. Parents who demonstrated $< 80\%$ fidelity on the RIT-PFF and/or who didn’t report increases in the EIPSES were directed

into coaching. Coaching involved videoconferences once per week (wks. 6-10) with a parent coach (first author), and followed the occupational performance coaching model which assists parents in creating an environment that is more suited for themselves and their child to succeed (56). Sessions included review of successes and challenges, parent practice with feedback, problem solving, and planning.

Waitlist Control (WLC). Participants in the WLC group were provided with information about available community resources after randomization. These participants were given the opportunity to engage in the stepped-care format of Online RIT after the post-intervention data collection time point; however their data was included exclusively in control group analyses.

Post-Intervention (15 weeks). Participants returned to RUMC for post-intervention assessments of parent functioning and child social communication. Fidelity was coded from home-based parent-child interactions immediately after the clinic visit.

Data Analysis

Data on families who completed the study were analyzed using IBM SPSS Statistics, Version 22. Initial analyses included examination of baseline group equivalence using independent sample t-tests. Data were inspected for violations of the assumptions for each test prior to running it and were analyzed accordingly. Analysis of Covariance (ANCOVA) was used to evaluate treatment outcomes by comparing outcome measures at 15 weeks between the Online RIT and WLC groups, after controlling for T1 scores. Descriptive statistics were examined to characterize the acceptability of the stepped-care model of Online RIT and the related technology.

Results

Descriptive statistics for demographic characteristics and baseline outcome variables are provided in Table 1. Tests of group equivalence showed no significant differences in baseline variables. Outcome data did not violate assumptions for ANCOVA.

Table 1 should appear here

Parent Outcome Measures

ANCOVAs were run to determine the effect of the stepped-care model of Online RIT on post-intervention parent variables after controlling for baseline scores on these same variables (Table 2). After adjusting for baseline scores, there were significant differences in post-intervention outcomes between groups on ratings of parent fidelity, $F(1,12) = 44.59, p < .05$, Cohen's $d = 3.86$, and EIPSES scores, $F(1,12) = 6.185, p < .05$, Cohen's $d = 1.44$. Post hoc analyses were performed with a Bonferroni adjustment and indicated that post-intervention parent fidelity ratings were statistically significantly greater for Online RIT relative to WLC ($M_{diff} = 2.56, 95\% \text{ CI } [1.72, 3.39], p < .05$). Post-intervention EIPSES scores were also statistically significantly greater for Online RIT vs. WLC ($M_{diff} = 9.86, 95\% \text{ CI } [1.22, 18.50], p < .05$). Moderate effect sizes favored the Online RIT group on FQOL (Cohen's $d = .75$); however, these differences were not statistically significant.

Individual differences in response to Online RIT were observed such that only one parent was considered a full responder after the website alone, as they met the parent fidelity threshold and demonstrated increases in self-efficacy. Two parents who met criteria for fidelity of RIT reported slight declines in self-efficacy from baseline to

post-website, and therefore received coaching. Four additional parents received coaching as they did not meet RIT fidelity threshold. Five of the parents who received coaching achieved fidelity and increased ratings of self-efficacy from baseline to post-intervention.

Child Outcome Measures

ANCOVAs were run to determine the effect of Online RIT on post-intervention child variables after controlling for baseline scores on these same variables (Table 2). After adjusting for baseline scores, there were significant differences in post-intervention outcomes between groups on SCC Total scores $F(1,12) = 4.863, p < .05$, Cohen's $d = 1.27$. Post hoc analyses were performed with a Bonferroni adjustment. Post-intervention SCC Total scores were significantly higher in the Online RIT group relative to WLC ($M_{diff} = 17.267, 95\% CI [.160,34.374], p < .05$). A large effect in favor of the Online RIT group was observed for the UIA (Cohen's $d = 1.26$), although this difference was not statistically significant.

Although differences in the UIA were non-significant, the large effect size suggested utility of follow-up analyses to evaluate individual participants' scores. As such, reliable change index analyses were calculated using the Leeds Reliable Change Index (57) to determine significant individual changes in UIA performance across the sample. Results suggested that 3 out of the 7 children in Online RIT demonstrated reliable improvement in performance on the UIA while no children from the control group showed similar reliable improvement. Further, one participant from the control group demonstrated a reliable decline in UIA performance. None of the children in the Online RIT group showed reliable decline in UIA performance.

Table 2 should appear here

Acceptability

Descriptive statistics were examined to characterize the acceptability of the stepped-care model of Online RIT and the related technology as rated by participants who completed the program (Table 3). Responses on the STP indicated strong acceptability of RIT as a skill building intervention. Participants rated RIT as very safe and effective, and endorsed items such as "good fit". Average scores across the Online RIT Attributes scale suggest that as a technological innovation, Online RIT has strong potential for adoption. Responses suggest that Online RIT is acceptable, relatively easy to use, and families supported items such that the intervention is easy to "see" and "explain to others" as to why Online RIT is user-friendly. Further, responses suggest that while Online RIT is consistent with other services a child receives, it also offers unique information that parents find helpful.

Table 3 should appear here

Discussion

The current proof-of-concept study is the first to evaluate a stepped-care telehealth parent training program for delivering ASD-specific intervention. Indeed, families of young children with or at-risk for ASD experience significant uncertainty and stress during the period that they are waiting for an evaluation and initiation of comprehensive early intervention services (58). In addition, many children are "missing out" on intervention during a critical period of brain development (2). Thus, the development and evaluation of innovative interventions and delivery models, such as Online RIT, with potential to deliver timely, equitable and cost-efficient ASD-specific intervention to young children is critical.

After adjusting for baseline scores, parents in the intervention condition showed significantly larger improvements in parent fidelity of RIT and parent self-efficacy. While it is not surprising that parents who received Online RIT learned the strategies better than parents who did not receive the program, these data support the notion that Online RIT can be an effective model for parents to learn ASD-specific intervention strategies and change their behavior accordingly during interactions with their young children at home. All but one parent in the Online RIT condition eventually implemented RIT at or above the a priori fidelity threshold. Prior research has found that despite overall improvements in skill after telehealth training, many parents still do not achieve the fidelity threshold; for example, only five out of 14 parents met the fidelity threshold after telehealth training in ESDM (32). It is important to note that these predetermined fidelity thresholds are a legacy from lab-based efficacy studies, and the necessity or impact of achieving the fidelity threshold remains unclear in parent-mediated intervention studies. Nonetheless, results from the current study suggest that a brief targeted NDBI like RIT may be easier to learn via telehealth relative to comprehensive NDBIs.

Data from the current study also suggest a meaningful relationship between Online RIT and parental cognitive and motivational outcomes like self-efficacy, which is consistent with prior research of parent training in NDBIs (59). Self-efficacy is an important driver of individual behavior change (60), with higher self-efficacy related to a greater likelihood of embracing and sustaining novel behaviors, even when faced with obstacles (61). It is possible that parents who feel more efficacious in interactions with their child with ASD may engage with their child more often, have higher expectations for their child's behavior, and/or more effectively advocate for their child's needs, all of which may contribute to improved parent and child level outcomes, especially during a time of uncertainty and need. Interestingly, two parents who were observed to be implementing RIT with fidelity after using the website alone reported experiencing declines in self-efficacy during that same period. It is possible that these parents reflect a subset of individuals who may need more support, and at earlier stages, to enhance parenting efficacy in response to such a program. Additional research is required to determine how to optimize interventions to meet the needs of individual families in a timely and effective manner.

No significant differences between the two groups on broad family quality of life at post-intervention were observed. This is an area that is often not directly measured within early intervention for ASD trials, as primary outcomes tend to be related to the child (e.g., social communication, developmental functioning) or to the parents' use of the intervention techniques (e.g., fidelity of the intervention;(62). However, enhancing a family's capacity to problem solve, advocate and seek out supports are considered critical outcomes of Part C (Individuals with Disabilities Education Improvement Act of 2004 [IDEIA]) Early Intervention programs. Emphasizing such family-level outcomes in studies of parent training interventions for young children with ASD may be key in improving long-term outcomes and for increasing the adoption and sustainability of such programs in community settings such as Part C (63).

After adjusting for baseline scores, children in the intervention condition had improved scores on parent report of overall social communication skills. Although significant differences between the two groups were not observed on the UIA, a large effect size favored the intervention condition with three of these children showing reliable improvement in their UIA performance. The failure to observe statistically significant effects of the intervention on UIA may be driven by the small sample size. Further, standardized clinician-administered social communication assessments as primary endpoints command a high threshold that may not be sensitive to subtle markers of change in early social communication skills (64). Thus, it is possible that a certain amount of time and intensity

of intervention may be necessary for generalized social communication gains to be observed on the standardized clinical assessments (64).

The extent to which parents actually practiced and implemented these strategies with their children day-to-day is unknown. This metric, often referred to as enactment or dose, is extremely challenging to measure and is historically under-reported in studies of parent mediated interventions for ASD and related conditions (55, 65). In the current study, a text message approach to collecting this data was trialed. First, the study team text messaged three times per week (“Have you used RIT with your child today? Y/N”; if Y “For about how many minutes did you use RIT today?”). Although families initially responded, the response rate dropped to zero after about two weeks. Parents reported that these texts were “too frequent,” so the rate was reduced to once a week, but the similar response rate was observed. The study team then requested that families complete an Online RIT practice log calendar by filling out the approximate number of minutes spent practicing RIT with their child each week directly into the website. Unfortunately, a programming error made it impossible for the study team to track this information from the administrative end. This process evaluation data has encouraged consideration of ways to incorporate data collection directly into the technology (e.g., a pop-up calendar that emerges when a family signs on to the website). A critical area for future research will be to work with families and other key stakeholders to determine acceptable, effective and feasible strategies for collecting this critical enactment data.

Limitations

Several limitations to the current study have been noted in the discussion section including the small sample size, lack of enactment data, and a lack website engagement data. It is acknowledged that telehealth may not be a universally acceptable and/or effective platform for all families. Further, this study was not able to address questions related to which variables predict program engagement and treatment response; such work will be critical for determining, a priori, which families may benefit from such a delivery model and which families may be better served via an alternative model. In addition, the waitlist control study design limits the strength of the conclusions that can be drawn from this work and requires close consideration of the ethical and practical implications of placing families on waitlists during a time of vulnerability for the child and family.

Conclusions & Future Directions

With the limitations above noted, the current proof-of-concept study still serves as an important initial step in exploring the feasibility of a stepped-care format of Online RIT. We found that parents enjoyed the intervention content and website, and that they were able to learn and use RIT with their children as a result of the program. These data are encouraging and provide a context for important future directions. Indeed, we selected parent fidelity of RIT and parent self-efficacy as tailoring variables in the current model based on theoretical rationale, but by design we were not able to explicitly test whether these are the “right” tailoring variables or the extent to which different levels of care predicted specific response to treatment across outcomes of interest. In addition to identifying appropriate tailoring variables, a related critical next step of this research is to empirically test the efficiency and effectiveness of possible active components of the intervention (e.g., parent coaching) and to understand the extent to which these components can be adjusted to provide more individualized intervention. Theoretically informed pilot data from this trial are critical for use of novel research strategies such as Multiphase Optimization Strategy (MOST; (33)) which has been posited as an alternative to the traditional randomized control/confirmatory trial in the development and evaluation of telehealth interventions. Indeed, planned future

research with Online RIT will capitalize upon such innovative research designs to create and evaluate an optimized adaptive telehealth intervention.

Abbreviations

ANCOVA: Analysis of Covariance

ASD: Autism spectrum disorder

CBT: Cognitive Behavioral Therapy

CEW: Computer-Email-Web

EIPSES: Early Intervention Parenting Self-Efficacy Scale

ESDM: Early Start Denver Model

FQOL: Family Quality of Life

IRB: Institutional Review Board

JASPER: Joint Attention Symbolic Play Engagement and Regulation

MOST: Multiphase Optimization Strategy

MSEL: Mullen Scales of Early Learning

NDBIs: Naturalistic Developmental Behavioral Interventions

RCT: Randomized Controlled Trial

RIT: Reciprocal Imitation Training

RIT-PFF: RIT Parent Fidelity Form

RUMC: Rush University Medical Center

SCC: Social Communication Checklist

STP: Scale of Treatment Perceptions

UIA: Unstructured Imitation Assessment

WLC: Waitlist Control

Declarations

Ethics Approval and Consent to Participate: The IRB at Rush University Medical Center (IRB 15100203) approved this human subjects trial. Participants signed informed consent at the in-person screening/baseline visit, before any data collection began.

Consent for Publication: Not applicable

Availability of Data and Materials: The datasets used and analyzed for the current study are available from the corresponding author on reasonable request.

Competing Interests: AW serves as a consultant and trainer in RIT for community-based organizations. CL, ZA, and LS declare that they have no conflicts of interest.

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Authors' Contributions: AW conceived of the study, participated in its design, performed the statistical analysis, and coordination and drafted the manuscript; CL participated in the analysis and interpretation of the data; ZA helped to draft the manuscript; LS participated in its design and helped to draft the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1. Participant demographic information

Characteristic	Intervention (n=10) (M, SD)	Control (n=10) (M,SD)
<u>Child Demographics</u>		
Male	8	6
Child Age in Months	40.10 (10.41)	35.40 (11.09)
Nonverbal Age Equivalent in Months	18.70 (6.68)	22.67 (8.41)
Expressive Language Age Equivalent in Months	9.5 (4.14)	14.13 (10.36)
<u>Child Race/Ethnicity</u>		
Asian	1	0
Black	4	0
Caucasian, Non-Hispanic	0	5
Hispanic/Latino	4	4
Multiracial	1	1
Hours of Intervention	7.3	5.06
<u>Parent/Family Demographics</u>		
Female	10	10
Parent Education		
Some High School	1	1
High School Degree	2	0
Some College/Specialized Training	3	3
4-Year College Degree	0	4
Graduate Degree	4	1
Employed Outside the Home	6	4
Parental Marital Status		
Married-living with partner	4	5
Single-living with partner	4	1
Single-living alone	2	2
Divorced or Separated	0	1
Computer Use and Literacy		
Very comfortable with computers	8	7
Very comfortable with internet	9	9

Daily use of computer at home	10	9
More than 5 times each day on the internet	6	5
More than 7 hours per week on the internet	5	5

Note. Range of intervention hours: Intervention (2.00-36.00), Control (0-33.00)

Table 2
Online RIT Parent/Family and Child Outcomes (n = 15)

Variable	Intervention		Control		ANCOVA			Pairwise	
	Adjusted M	SE	Adjusted M	SE	F	p	Cohen's D	Mean Difference	95% CI
Parent/Family Outcomes									
RIT Fidelity	4.33	0.27	1.77	0.26	44.59	0.00	3.86	2.56	1.72,3.39
EIPSES	118.19	2.88	108.33	2.70	6.19	0.03	1.44	9.86	1.22, 18.50
FQOL Total	108.02	2.72	103.20	2.55	1.68	0.22	0.75	–	–
Child Outcomes									
UIA	8.54	1.33	4.40	1.24	4.75	0.05	1.26	–	–
SCC Total	146.61	5.72	129.34	5.35	4.84	0.05	1.27	17.27	0.16,34.37
Note. EIPSES = Early Intervention Parenting Self Efficacy Scale; FQOL = Beach Center Family Quality of Life Scale; UIA = Unstructured Imitation Assessment; SCC = Social Communication Checklist.									

Table 3
 Acceptability of Online RIT (n = 15)

Acceptability Outcomes	M (SD)
Scale of Treatment Perceptions	
RIT Safety	6.67 (0.39)
RIT Effectiveness	6.61 (0.34)
RIT Family Fit	5.81 (1.08)
Online RIT Attributes	
Online RIT Relative Advantage	6.00 (0.57)
Online RIT Acceptability	6.36 (0.54)
Online RIT Limited Complexity	6.00 (0.74)
Online RIT Observability	6.50 (0.60)
Note. Range of scores: (1–7).	

Figures

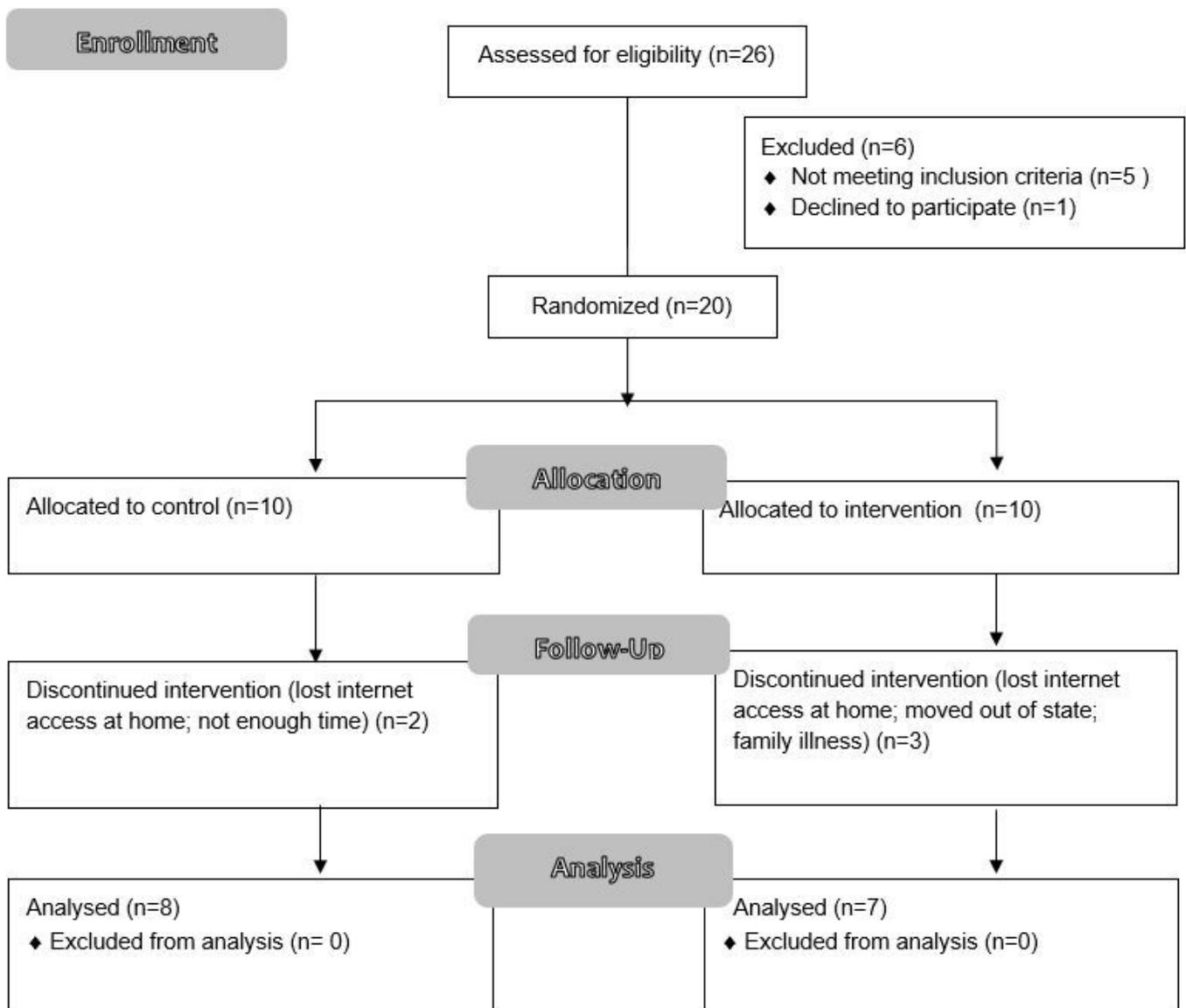


Figure 1

Figure 1