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Research Article

Scaling Evidence-Based Practice in Autism: A Randomized Clinical Trial of a Digital Parent trainer in Pivotal Response Treatment

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Abstract

The accessibility of evidence-based interventions (EBIs) for children with autism spectrum disorder (ASD) remains limited, creating a significant research-practice gap. This study aimed to address this gap by examining the efficacy of a digital parent trainer in delivering Pivotal Response Treatment (PRT), an evidence-based intervention for ASD. The digital trainer utilized e-learning technologies and video feedback to train parents in implementing PRT strategies. A randomized clinical trial was conducted with 10 children with ASD and their parents participating, the primary objective was to evaluate the effectiveness of the digital trainer in advancing the communication skills of children with ASD. Secondary objectives included assessing the trainer's effectiveness in teaching parents to implement PRT and evaluating the usability of the digital App. The study consisted of a 16-week intervention phase, during which parents received training through the application, uploaded videos of themselves implementing the strategies and received feedback in the form of a concise video with feedback embedded on their uploaded video, synchronized to the important interactions. The feedback was given by a person trained to provide video feedback. The clinical trial's control group received parental guidance through telehealth group meetings from a BCBA certified professional. Outcome measures included assessments of children's communication skills, parental fidelity of implementation (FiO) to PRT strategies, and parent-reported data. Blinding was maintained during the video coding process. The results indicate positive outcomes in the areas of children's communicative behaviors, parental FiO to PRT, and parent satisfaction with the digital app. The study highlights the potential of digital tools to scale up the delivery of evidence-based interventions for ASD, improving accessibility and empowering parents as key agents in their children's treatment journey. Further research is needed to validate these findings with a larger study group and explore the long-term effects of digital parent training in ASD interventions.

Keywords: ASD; Autism; PRT; Parent Training; Digital Training; App Training.

Introduction

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder characterized by persistent difficulties in social interaction, communication, and restricted or repetitive patterns of behavior. The prevalence of ASD has been steadily increasing, highlighting the need for effective interventions to support individuals with this condition.Evidence-based interventions (EBIs) have shown promising results in improving outcomes for children with ASD. However, despite the availability of these interventions, there is a significant research-practice gap, with many families facing barriers in accessing and implementing these interventions.

Despite the remarkable progress that has been made in developing evidence-based interventions (EBI) for autism, most children do not receive these top-quality treatments due to a prominent research-practice gap [1,2]. Considering the great benefits of early, intensive

and effective intervention for children with ASD, their parents and the economy [3], it is important to examine strategies that will help overcome this gap and make treatment available for all [4].

One key challenge is the limited availability of trained professionals who can deliver interventions directly to children with ASD. This shortage of specialized providers creates long wait times and geographical disparities in accessing services, especially in remote or underserved areas. As a result, parents often play a crucial role in delivering interventions and supporting their child's development. Empowering parents with the necessary knowledge and skills to implement evidence-based strategies is therefore critical in bridging the research-practice gap and improving outcomes for children with ASD. One strategy for increasing the accessibility of top quality treatment is the use of digital tools [4]. The dominant model for treatment today (One-to-one, in-person treatment, with a trained mental health professional), is very limited due to its dependence on the number of available therapists, their geographical location and their expertise in EBI. The use of technology to deliver interventions offers promising directions for overcoming some of these limitations - by making treatment more flexible, less dependent on location, and easier to scale. For example, some "Telehealth", web-based treatments are administered one-to-one by a mental health professional but do not require the client to go to a clinic [5]. Other options, based on "E-learning" technologies, may involve no therapist but rather try to transfer core principles of intervention programs through video clips, automated chats and assigned homework that patients can complete at home [6,7]. By reducing the need for expert time, these "E-learning" treatments have an even greater potential to impact large numbers of individuals.

Multiple options for such "E-learning" treatments are available online for the treatment of anxiety and depression [8], and demonstrations of their efficacy and ability to reach large scale populations are starting to emerge. For example, in one study cognitive behavioral treatment was provided online as a course [9]. Support to patients was provided by a trained therapist by phone or email on a weekly basis. Despite the required involvement of a qualified clinician, the protocol still allowed larger scale application of treatment than usual (mean therapist time per case was 112 min, 1471 individuals completed treatment). At posttreatment and follow-up, reliable recovery ranged from 46.7% to 51.1%, demonstrating the potential of these interventions to assist many individuals.

Traditional parent training programs have been successful in enhancing parent-implemented interventions. However, these programs often require parents to attend in-person sessions, which can be time-consuming, costly, and logistically challenging for many families. Furthermore, the COVID-19 pandemic has further emphasized the need for alternative delivery methods that minimize face-to-face interactions. Digital technologies offer promising solutions by providing accessible, flexible, and cost-effective platforms for delivering parent training interventions.

Digital parent training interventions utilize e-learning platforms, multimedia resources, and interactive modules to deliver evidence-based strategies to parents. These interventions have the potential to reach a larger number of families, reduce geographical barriers, and provide ongoing support and guidance in a convenient and individualized manner. Moreover, digital platforms can incorporate features such as video demonstrations, self-paced learning, and progress tracking, which can enhance parents' understanding and implementation of interventions.

In the area of autism, there is great potential for using digital tools to train parents to implement EBI. Parent training is an especially cost-effective and ecologically valid way to bolster the amount of intervention a child receives. With respect to ASD, parent training and family involvement in intervention has been cited as a fundamental component of effective intervention programs [10]. A significant body of literature suggests that parents can be successfully trained in techniques to improve social communication skills in children with ASD [11-13]. However, there are significant barriers associated with accessing parent training programs via clinic-based service delivery models. Limited financial resources, limited transportation, lack of child care, geographic isolation, lengthy waitlists, and extensive time commitments have all been cited as obstacles to participation in traditional parent training programs [14,15]. As such, there is an identified need for the adaptation of parent training in EBI to nontraditional service delivery models [16]. The use of digital technologies may provide one avenue for doing so. Initial evidence has even demonstrated how technologies can be successfully used to train parents in EBI. For example, in several studies, high risk parents and parents of children at risk were successfully trained in behavior management strategies and general adaptive parenting techniques using digital intervention tools [16,17]. However, there is limited research empirically evaluating the use of such programs to teach intervention strategies to parents of children with ASD. One small randomized control study Nefdt, Koegel, Singer and Gerber [18] used a DVD-based self-directed distance learning program to introduce 27 primary caregivers of children with ASD to pivotal response training (PRT), an evidence-based naturalistic behavioral intervention. Results of this study indicated that parents in the treatment group showed more improvement in the ability to implement PRT techniques and provided significantly more language opportunities than parents in the control group. In addition, children in the treatment group used significantly more functional verbal utterances than those in the control group. This study suggests that both caregivers and their young children with ASD were able to benefit from participation in a self-directed, distance learning program.

This paper evaluates the effectiveness of a digital parent trainer in delivering Pivotal Response Treatment (PRT), an evidence-based intervention for ASD. We aim to contribute to the growing body of knowledge on digital interventions for ASD and to bridging the research-practice gap in accessing and implementing evidence-based interventions for children with ASD.

Clinical Trial Objectives

The study was intended to examine the effectiveness of a digital trainer for parents of children with ASD, in training them to implement evidence-based PRT interventions with their children and improve children's language communication skills.

The primary objective of this study was to evaluate the effectiveness of SocialMind's digital trainer in advancing the communication skills of the subjects with ASD.

Secondary objectives included an evaluation of the effectiveness of SocialMind's digital trainer in enhancing parents' ability to apply PRT techniques.

Secondary objectives also included examining the feasibility and acceptability of the digital parent training intervention from the perspective of parents. We explored factors such as accessibility, convenience, user-friendliness, and satisfaction with the intervention.

Methods

Trial design

Study Duration

This prospective study is expected to last no longer than 16 weeks per subject and no longer than a total of 24 months total for all subjects. Each subject remained in the study for a period of 16 weeks.

Design of the Clinical Investigation

This study was a pre-post study of the effectiveness of SocialMind's Digital trainer, and served as a preliminary study before conducting a more comprehensive RCT. Conducting such preliminary studies is a common practice. One example of a pilot for parent training in PRT using a pre-post design can be found under Steiner and colleagues [19].

Blinding and Masking

The study was blinded in the sense that evaluation of participant videos was blind. The study was not masked.

Participants

Number Of Participants: 10 subjects, male or female, with an ASD Diagnosis. Inclusion Criteria:

- Male or female aged 1.5-6 years
- Diagnosed with Autism Spectrum Disorder according to the DSM-5 Criteria, based on previous reports from appropriate professionals.
- Severity of symptoms for cluster A (Referring to communication and social abilities) in the last updated report is 2-3.

Exclusion Criteria:

- Subjects who had ever tried PRT treatment.
- Substantial changes in pharmacological or behavioral treatments in the month prior to study enrollment or during intervention.
- Evaluation by the Principal Investigator (PI) indicating the unsuitability of the subject or subjects' family in carrying out the requirements of the study.

Withdrawal Criteria:

- Upon decision of the regulatory bodies
- Upon request of one of the legal guardians
- Subjects whose parents fail to complete at least 2 of the 6 strategy modules in the digital trainer. These were considered dropouts. A drop out rate of 10-20% was expected.

Data Collection: Data was collection online in several forms:

- Initial intake by the study coordinator took place over Zoom
- Questionnaires were emailed by participant parents
- Videos used for evaluation pre and post study were emailed by participant parents

Baseline Assessment

Once found to be suitable for the study, parents of the participants (Children with ASD) sent a baseline video of themselves interacting with their child. This video included at least 10 minutes of interaction, in which the parents were asked to try and get their child to communicate as much as possible. This video was coded for parental fidelity for PRT Strategies i.e. Shared control,

Natural reinforcement, Immediate and dependent reinforcement, Following the child's lead, Interspacing and diversifying.

Raters also tallied the child's frequency and length of verbal utterances and also specified utterance type (unintelligible, imitative, verbally prompted, nonverbally prompted, or spontaneous). Multiple-word utterances were scored as a single instance of communication. The child's use of initiative joint attention was also tallied.

In addition, parents were asked to complete the Vineland 2 communication subscale regarding their child with ASD [20].

Interventions

Intervention phase, weeks 1-16: Following the assessment the parents received a link to SocialMind's digital trainer. The digital training was provided to the parents as a software they could use on their cellphones. The digital training included six modules, each training the parents in one PRT strategy:

- Shared control
- Child choice
- Reinforcement
- Prompting
- Diversifying
- Insterspacing

Each Module included 4 segments:

- Interactive animated scenarios- through them the parents learned about each strategy
- Quizzes on real life video examples - Through them parents saw how implementation in the real world looks and they practiced what they have learned.
- Library of customized ideas for implementation in the children's natural environments.
- Parents were free to use the digital modules at their own pace and repeat them as many times as they felt needed. After watching the modules, parents uploaded between one to three 5 minutes videos of themselves implementing the learned strategy with their child. Videos were uploaded to a secured server owned by SocialMind. After uploading a video, parents received feedback as recorded narration on the video they have uploaded. The feedback focused exclusively on the strategy learned on the specific module. Feedbacks were written and recorded by socialMind's clinical team. Participating parents were required to upload a video at least once a week.

Control Intervention

Parents in the control group participated in group meetings of parental guidance, guided by a Board Certified Assistant Behavior Analyst (BCaBA, certified by the BACB) who was not part of SocialMind's team and was not familiar with the details of the clinical trial.

Meetings took place once every two weeks for 90 minutes over Zoom and each had a pre-planned subject. The subjects included methods to prevent difficult behavior, daily schedules, methods to follow the child's initiatives and other relevant subjects.

Intervention completion

Upon 16 weeks subjects were evaluated at the end of the study using the same measures as those detailed in the baseline phase:

Parents sent a 10 minutes video of an interaction with their child, which was tallied for parental fidelity and child's communicative behaviors. In addition, parents completed the Vineland 2 communication subscale regarding their child with ASD again [20].

Outcomes

Primary outcomes

The primary outcome of the research focused on the child's communicative behaviors during a 10-minute interaction video with the parent. These behaviors were measured at baseline and post-intervention to assess the effectiveness of the intervention. The coding of the videos followed established methods used in previous research [21,22]. The coding process included analyzing the frequency and length of utterances as well as the frequency of initiative joint attention.

Secondary outcomes

Secondary outcomes included additional measures to further evaluate the intervention's impact.

1. **Parental Implementation Fidelity**: The 10-minute interaction videos was also be coded to assess the fidelity of parental implementation to Pivotal Response Treatment (PRT). This coding followed established methods outlined in published research [21,23]. The fidelity assessment was conducted both at baseline and at week 16 to monitor changes in parental implementation throughout the intervention.

2. **Vineland-2 Communication Subscale:** The Vineland-2 communication subscale was used as a secondary outcome measure. This assessment, developed by Sparrow, Cicchetti, and Balla [20], was administered at baseline and post-intervention. It aimed to capture changes in communication skills specific to the child with Autism Spectrum Disorder (ASD).

3. **Satisfaction Questionnaire:** A satisfaction questionnaire, designed by the clinical team, was given to the parents. For the test group, the questionnaire was focused on assessing the usability and functionality of the digital trainer. The control group completed a satisfaction questionnaire at the request of the parental guidance group's guide, and the results were shared with the guide.

By examining these outcomes, the study aimed to evaluate the impact of the intervention on the child's communicative behaviors, parental implementation fidelity, communication skills, and satisfaction with the digital trainer.

Randomization

Sequence generation

Trial participants were matched for gender and age (one year increments), in each pair we used the random function in the Microsoft Excel software to decide who goes to the trial and who to the control. Six pairs of participants joined the trial, and by the time the trial was stopped (earlier than expected) all six control group participants finished the intervention, while only four of the test group participants finished the intervention.

Allocation concealment mechanism

Trial participants were assigned numbers according to the time they entered the trial. These numbers were used to identify the 10-minute videos each family uploaded before and after the intervention. The people coding these videos were exposed only to identification numbers, in order to conceal the type of intervention each family received.

Blinding

Blinding was in place for the people who coded the participant videos, both before and after the intervention. In order to enforce blinding, the allocation was kept secret from most of the SocialMind team. The people who were exposed to the allocation were the trial coordinator, the feedbacker and the head of SocialMind's clinical team who sometimes advised regarding details of the feedback process. Members of the technical team who maintained the mobile app were exposed to the identity of the trial group, but they had no direct interaction with trial participants.

Participant flow

Participants were recruited over Facebook, via groups of parents of children with autism. After approaching the trial coordinator, the parents had a zoom call of about an hour with the coordinator, where they received information regarding the study, and the match of the family to the acceptance criteria was tested.

After signing a request to enter the trial the parents were requested to fill and email the completed Vineland 2 communication subscale regarding their child. They were also required to record and email a video with at least 10 minutes of interaction, in which the parents were asked to try and get their child to communicate as much as possible.

The trial intervention started on the first Sunday after both these requirements were fulfilled. After 16 weeks of intervention the parents were required to fill the Vineland 2 communication subscale and to record and send a 10 minute video, following the same instructions as in the pre-trial assessment.

Recruitment

Participant recruitment started in July 2022, the first family entered the trial on August 3rd 2022. Recruitment was halted in September 2022.

The trial was stopped because SocialMind entered financial difficulties. At the time of trial termination, ten participants completed it, four in the trial group and six in the control group.

Baseline data

All trial participants were families with a child between the ages of 2 years and 8 months and 3 years and 10 months, who was diagnosed with Autism Spectrum Disorder according to the DSM-5 Criteria, based on previous reports from appropriate professionals. All the children were male. The families were all Hebrew speaking Israelis, where at least one parent had a smartphone and could use it to download and operate the SocialMind app.

No. analyzed

The test group consisted of four families, the control group consisted of six families.

Results

Primary Outcome

		Length of Utterance		Frequency of Responsive Communication/ 10min		Frequency of Initiative Communication/ 10min		Frequency of Joint Attention/ 10min	
		test	ctrl	test	ctrl	test	ctrl	test	ctrl
pre	Mean	1.1	0.96	8.5	8.83	18.25	6.33	1.75	1.50
post	Mean	1.84	0.81	19.50	8.5	45.25	22.50	11.50	5.33
Post - Pre Improvement	Mean	0.74	-0.15	11.00	-0.33	27.00	16.17	9.75	3.83
	STD	0.66	0.34	11.11	8.89	13.74	27.70	8.02	9.50

Table1

The primary outcomes of this study focused on two key measures: joint attention and length of utterance. These measures were assessed by analyzing the numerical results obtained from the 10-minute interaction videos between the child and the adult.

Joint Attention: The number of times the child engaged in joint attention per 10-minute session was recorded. Joint attention was defined as the child looking at the adult, shifting their gaze to an object, and then returning their gaze to the adult while making a request. Each instance of joint attention was counted as a separate occurrence.

Length of Utterance: The length of the child's utterances was measured in whole words. If an utterance contained unintelligible sounds that were not recognizable as words, it was counted as half an utterance.

Mann-Whitney U test

In order to assess the difference of the test group outcomes from the control group outcomes we applied the Mann–Whitney U test to each of the four measures listed above. For each measure we calculated the U test of the difference between the post trial and the pre-trial values. The range of possible values for the U test is 0 to 24, and in case of statistically identical results for the test and control group the test value would be 12 on average (n_{test}=4, $n_{control}$=6). The results show a significant difference between the test and the control groups, the children's communication skills in the test group improved much more than in the control group, in all measured parameters.

	Length of Utterance	Frequency of Responsive Communication/ 10min	Frequency of Initiative Communication/ 10min	Frequency of Joint Attention/ 10min
Mann–Whitney U test Result	22.0	19.0	18.5	20.0

Table 2: The U test results calculating the difference between the post trial and the pre-trial values.

Secondary Outcomes

		Fidelity of Implementation by Parent		Vineland 2 communication subscale	
		test	ctrl	test	ctrl
pre	Mean	33.93	20.95	22.25	13.5
post	Mean	92.14	29.52	23	20
Post - Pre Improvement	Mean	58.21	8.57	0.75	6.5
	STD	11.8	28.41	2.87	6.5

Table 2: The U test results.

The secondary outcomes of this study encompassed additional measures that provided a comprehensive assessment of the intervention's effects. These measures were evaluated based on the numerical results obtained from the 10-minute interaction videos and other assessment tools.

Parental Implementation Fidelity: The videos were coded to assess the fidelity of parental implementation of Pivotal Response Treatment (PRT), following established methods outlined in previous research [21,23]. This coding aimed to measure the degree to which parents successfully implemented PRT techniques during the interactions, both at baseline and at week 16. Scoring was done by a person certified to Level 5 (Train the Trainers) by Koegel Autism Center in Santa Barbara, California. The fidelity score has a maximum value of 100, indicating optimal implementation.

Vineland 2 Communication Subscale: The communication subscale of the Vineland Adaptive Behavior Scales, Second Edition (Vineland 2) was utilized to evaluate the child's communication skills. This standardized assessment tool, administered both at baseline and post-intervention, provided a comprehensive measure of the child's communication abilities within various contexts [20].To gauge parental satisfaction, an anonymous parent satisfaction questionnaire was administered separately to both the control group and the test group. Five participants from each group completed the questionnaire, with the test group including at least one participant whose intervention was terminated prematurely when the trial was halted. All responses were collected prior to the trial's discontinuation.

The questionnaire included the following question, translated into Hebrew: "How pleased are you with the guidance you received?" Participants were asked to rate their satisfaction on a scale from 1 to 5, where 1 represented low satisfaction and 5 indicated high satisfaction. The average response from the test group was 4.8, with a standard deviation of 0.4. The control group's average response was 4.0, with a standard deviation of 0.9.

Discussion

Limitations

1. **Sample Size and Generalizability:** The study's sample size was small, which may limit the generalizability of the findings to a larger population. It is important to acknowledge that the characteristics and needs of the participants in this study may not fully represent the diverse range of individuals with autism spectrum disorder (ASD).

2. **Selection Bias:** There was potential for selection bias as the participants were recruited through specific channels, namely parent groups on Facebook. This may have introduced a bias towards individuals who were already motivated or had access to these resources, thereby limiting the representativeness of the sample.

3. **Self-Report Measures:** Some of the outcomes, such as the parent satisfaction questionnaire, relied on self-report measures. Self-report measures may be susceptible to response bias or subjective interpretations, potentially impacting the accuracy and objectivity of the reported results.

4. **Short-Term Follow-up:** The duration of the intervention and the follow-up period in this study were relatively short. Longer-term follow-up assessments would provide a more comprehensive understanding of the intervention's sustained effects on the communication and developmental skills of children with ASD.

5. **Lack of Control for Parental Factors:** The study did not control for various parental factors, such as prior experience with interventions or education level, which could influence the outcomes.

Generalizability

Although the SocialMind mobile App used in this study is currently inactive due to financial constraints faced by the company, we believe that the study's results can be replicated with other similar software tools that are based on the principles of Pivotal Response Therapy (PRT). The emphasis on utilizing a well-defined clinical method is crucial as it minimizes the potential variability that could arise from individual differences in generating and providing feedback on the videos uploaded by participating families during the intervention. While the specific technology used in this study may not be readily available, the underlying principles and strategies of PRT can be implemented through various digital platforms or interventions.

Furthermore, the reduction in variability resulting from the application of a standardized clinical method enhances the reproducibility of the findings. This allows for greater confidence in the generalizability of the study's results to similar interventions or programs utilizing PRT principles, irrespective of individual clinician styles or variations in feedback generation and presentation.

Interpretation

The findings of this trial demonstrated a clear advantage of the intervention method utilizing Pivotal Response Therapy (PRT) principles over the control method in improving verbal communication skills in children with autism spectrum disorder (ASD). The results indicate significant improvements across all four measured scales, highlighting the efficacy of the intervention in enhancing children's communication abilities.

First, the average length of utterance by the children substantially increased in the trial group, from 1.1 words to 1.84 words on average. In contrast, the control group showed a decrease, from 0.96 words to 0.85 words. This difference emphasizes the positive impact of the intervention on promoting longer and more expressive verbal communication in children with ASD.

Second, the average frequency of responsive communication in the trial group demonstrated a remarkable improvement,

increasing from an average of 8.5 times per 10 minutes to 19.5 times. Conversely, the control group did not show a significant change in this aspect. This finding suggests that the intervention effectively enhanced children's ability to engage in reciprocal and responsive communication with their parents.

Third, both groups exhibited an increase in the average frequency of initiative communication. However, the trial group demonstrated a larger increase, with the average frequency rising from 18.25 times per 10 minutes to 42.25 times, compared to the control group's increase from 6.33 times to 22.5 times. This indicates that the intervention not only facilitated responsive communication but also encouraged children to take the initiative in communication interactions. Lastly, the frequency of joint attention, an essential component of social communication, also improved in both groups. However, the trial group exhibited a more substantial increase, with the average frequency rising from 1.75 times per 10 minutes to 9.75 times, while the control group's increase was from 1.5 times to 3.8 times. Additionally, the parent fidelity of implementing the PRT principles showed a significant improvement in the trial group, with aa average score increase of 58.2. In contrast, the control group demonstrated an improvement of only 8.6.

In conclusion, the trial results provide robust evidence supporting the superiority of the intervention method over the control method in improving verbal communication skills in children with ASD. The significant improvements observed in the length of utterance, frequency of responsive communication, initiative communication, joint attention, and parent fidelity underscore the efficacy of the intervention in promoting various aspects of communication.

These findings have important implications for the development and implementation of evidence-based interventions grounded in PRT principles for children with ASD. Further research and replication of the study findings are warranted to validate and extend these results in larger and more diverse populations of children with ASD.

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